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# DIRECTORY

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**Summer 1993**

Community Consortium
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# Foreword

Open Letter to People with HIV:

This directory gives you information about clinical trials in the Bay Area that people with HIV can join. As a person who has been in an HIV clinical trial, I'd like to point out some things you might consider if you're thinking about joining a trial.

There are at least two very good reasons to join a trial. First, you could be be helped by the new treatment. Second, you will be helping other people with HIV because we will learn which treatments really work, and which are unsafe. This kind of altruism has its benefits -- it makes you feel good.

But trials will take up some of your time. You may have to take time off from work, or you may need to get childcare. Be sure you understand the time commitment required in the study, and see if you can realistically meet it.

Don't rely on clinical trials as your only way of getting medical care. Though you will receive good medical attention (such as blood tests and physical exams) while you are in the study, you need to have your own health care provider for routine medical care.

To know if you are eligible for a trial, you need to know about your own medical history. What is your T-cell count? Have you had an HIV-related opportunistic infection? Are you allergic to any drugs? In reading this directory, you may find trials that you are interested in, but cannot join because you don't match the "eligibility" criteria.

Ask questions. Each one you ask will be a good one. Don't join a trial because you think you may be getting something for nothing. That won't be the case. However, you will get something by giving something.

And last of all, you will have to remember to take the treatments at specific times of the day or week. This is actually easier than it sounds, but takes some getting used to.

Good luck with your health. And if you decide to join a clinical trial, thank you for doing something positive for your health, and mine.

Pierre Ludington
Commissioner
San Francisco Health Commission

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**Mr. Morgan Fine**

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N01 - AI - 95035

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Research staff at more than 30 Bay Area trials sites who furnished the bulk of the information contained in the **Directory**. Without their considerable expertise and generous contribution of time and energy this project would not have been possible.

AIDS Treatment Resources, Inc., portions of whose glossary were adapted for use in the **Directory**.

*Bulletin of Experimental Treatments for AIDS (BETA)* which compiled information on drug assistance programs.

**Directory Editorial Staff:**

Zach Weingart
Nicolé Mandel
Thomas Mitchell

The **Directory of HIV Clinical Trials in the Bay Area** is published three times per year by the Community Consortium. The **Directory** contains information on clinical trials currently enrolling patients in the greater San Francisco Bay Area. No endorsement is made of any trial described herein.

Every reasonable effort has been made to ensure that the information presented in the **Directory** is accurate, comprehensive and up-to-date. However, eligibility and other criteria are subject to change, and trials may close to patient enrollment at any time.

The Community Consortium welcomes information about clinical trials available throughout the Bay Area for publication in the **Directory**. Any trial which has been reviewed and approved by an Institutional Review Board may be included. Anyone with information appropriate for publication here is asked to call the Consortium office at 415/ 476-9554.

An Association of
Bay Area HIV
Health Care Providers

The Community Consortium is affiliated with the
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University of California, San Francisco.

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# How to Use This Directory

The **Directory** is written for people who are living with HIV disease and for their health care providers. It should be used as one resource among many in learning about and managing HIV disease. The **Directory** will probably be most useful to people who already know something about their own health, and about HIV. If you think you need to learn more, talk to your health care provider and contact some of the Resources beginning on page 77.

## Understandable language

One of the stumbling blocks for many people in learning about HIV and clinical trials is confusing "medical jargon." We have tried to avoid using technical language whenever possible, but sometimes there is no simple way to describe technical information. If you come across a word or idea that you don't understand, you can check the Glossary on page 81. It may be helpful to discuss any remaining questions with your health care provider, or the contact person listed for the clinical trial. More information will also be available from one or more of the Resources listed on pages 77 through 79.

## Questions about clinical trials, and issues for special groups

To answer some important questions about clinical trials, and about who can join a clinical trial, we have included sections on common questions about clinical trials, how to join a clinical trial, and issues about clinical trials for women, children, youths and people who use injection drugs. These sections are found on pages 57 through 69.

## Trial Finder and Trial Descriptions

The 106 trials listed in the **Directory** are arranged by the disease or condition being studied, or by the group of people for whom the study is intended. Trial Finder on pages 3 - 6 and CD4 Cell (T-cell) Finder on pages 7 - 10 are quick references for trials you may be interested in.

If you are interested in a certain drug or treatments for a particular disease, you can also look it up in the Index on pages 89 and 90. The Index will tell you which page to turn to in the **Directory**.

*(continued)*

# How to Use This Directory

**For each clinical trial, we include the following information:**

**Title:** This is the official name of the trial. Some trials also have letters or numbers given in parentheses after the title. For example, ACTG 172 means this is AIDS Clinical Trials Group study number 196.

**Purpose:** This is what the researchers are trying to learn from the trial. Below are a few of the most common reasons why studies are done.

- To learn if a drug is safe for people to take.
- To learn if a drug works.
- To compare two or more drugs.
- To compare two or more doses of the same drug.

**About the study:** This section describes what will happen during a trial, from the patient's perspective. We tell you how long the trial lasts, if you will know what drugs you are taking, how the drug is given (for example, pill, liquid or injection), if there are an unusual number of required visits to the clinic, or if you need to stay in the hospital.

**Required:** These are the entry requirements that you must meet before you can join the study. These are sometimes called "inclusion criteria." We have space to list only a few of the most important entry requirements. In many cases, there will be others.

**Not allowed:** You cannot join the study if you fit any of these criteria. These are sometimes called "exclusion criteria."Again, only the most important exclusion criteria are included. You may not be able to join this particular study because there is a good chance that you would be harmed by the study drug. Researchers examine your medical history and your laboratory tests to make sure you are not at "high risk" for having harmful side effects. Many clinical trials require that your laboratory tests be "within normal limits," or at least in a safe range. This is to make sure you don't already have a medical problem that might become worse if you take the drug.

Women who are pregnant or breastfeeding may also not be able to join a clinical trial. This is because it is not known if taking the drug will harm the baby. Usually, women who have sex with men, and men who have sex with women, must agree to use birth control while they are in the study.

**Location:** This is where you need to go to participate in the study (the study "site"). We also give you the name of the person to call if you are interested. In most cases, you don't have to be a patient at the hospital or clinic where the study is located in order to join the study. For some studies, your doctor must contact the site first.

# Trial Finder

| Condition | Drug(s) | Page Number |
|---|---|---|
| Anal cancer in men | Observational study | 47 |
| Bronchitis treatment | Cefuroxime, augmentin | 44 |
| CMV retinitis treatment | Ganciclovir, foscarnet | 18 |
| CMV retinitis treatment | Oral ganciclovir | 19 |
| CMV disease prevention | Oral ganciclovir | 19 |
| CMV disease prevention | Oral ganciclovir | 20 |
| CMV disease prevention | HPMPC | 20 |
| Cryptococcal meningitis treatment | Macrophage-Colony Stimulating Factor (M-CSF) | 21 |
| Cryptococcal meningitis treatment | Amphotericin B, flucytosine, fluconazole, itraconazole | 21 |
| Cryptococcal meningitis treatment | Itraconazole, fluconazole | 21 |
| *Cryptosporidium* diarrhea treatment | Azithromycin | 43 |
| *Cryptosporidium* diarrhea treatment | Paramomycin (Humatin®) | 43 |
| *Cryptosporidium* diarrhea treatment | Diclazuril® | 44 |
| ddI-associated diarrhea | two different formulations of ddI | 44 |
| Fungal disease (*Aspergillus*) treatment | Itraconazole | 45 |
| Fungal disease prevention | Azithromycin, rifabutin, fluconazole | 32 |
| Fungal disease. *See also* Yeast infections | | |
| GYN screening | Pap smears, colposcopy | 49 |
| Herpes treatment | SP-303T | 22 |
| Herpes treatment | 256U87 | 22 |
| Herpes treatment | Trifluridine | 23 |
| Herpes prevention | 256U87, acyclovir | 23 |
| Herpes zoster treatment | 882C87, acyclovir | 24 |
| Herpes zoster treatment | BV-ara-U, acyclovir | 24 |
| HIV infection | AZT | 11 |
| HIV infection | AZT, ddC, ddI | 11 |
| HIV infection | any anti-HIV drug(s) | 11 |
| HIV infection | AZT, ddC, ddI | 12 |
| HIV infection | AZT, ddI | 12 |
| HIV infection | AZT, ddC, alpha interferon | 13 |
| HIV infection | 3TC, AZT, ddC | 13 |

# Trial Finder

| Condition | Drug(s) | Page Number |
|---|---|---|
| HIV infection | ddC | 13 |
| HIV infection | ddC | 14 |
| HIV infection | ddI, lentinan | 14 |
| HIV infection | d4T | 14 |
| HIV infection | Procysteine | 15 |
| HIV infection | CD4-PE40 | 15 |
| HIV infection | Curdlan sulfate | 16 |
| HIV infection | Passive hyperimmune therapy (ImmuPath) | 16 |
| HIV infection | THF-gamma 2 | 17 |
| HIV infection | Vaccine trial (gp120) | 17 |
| HIV infection | Vaccine trial (gp120) | 18 |
| HIV infection | Vaccine trial (gp160, VAXSYN®) | 18 |
| HIV infection in pregnancy | Vaccine trial (gp120) | 49 |
| HIV infection in women | Observational study | 49 |
| HIV infection in women | Observational study | 50 |
| HIV infection in pregnancy | AZT | 50 |
| HIV infection in mothers & children | Observational study | 50 |
| HIV infection in children | AZT | 51 |
| HIV infection in children | AZT, ddC | 51 |
| HIV infection in children | AZT, ddI | 52 |
| HIV infection in children | ddI | 52 |
| HIV infection in children | Vaccine trial (gp160) | 52 |
| HIV infection of the central nervous system | Observational study | 46 |
| HIV infection, heterosexual transmission | Observational stuy | 47 |
| Kaposi's sarcoma (KS) treatment | Intralesional velban injections | 25 |
| KS treatment | Activated CD8 cells plus IL-2 | 25 |
| KS treatment | Chemotherapy, ddC, ddI | 25 |
| KS treatment | Alpha interferon, ddI | 26 |
| KS treatment | DaunoXome, adriamycin, bleomycin, vincristine | 26 |
| Lymphoma treatment, Hodgkins | Bleomycin, vincristine, streptozocin, etoposide | 28 |
| Lymphoma treatment, non-Hodgkins | m-BACOD | 27 |
| Lymphoma treatment, non-Hodgkins | Etoposide, ifosfamide, mesna, G-CSF | 27 |
| *Mycobacterium avium* Complex (MAC) treatment | Azithromycin | 29 |
| MAC treatment | Azithromycin, GM-CSF | 28 |
| MAC treatment | TLC G-65 | 29 |
| MAC treatment | Clarithromycin, clofazimine, ethambutol | 29 |

# Trial Finder

| Condition | Drug(s) | Page Number |
|---|---|---|
| MAC treatment | Clarithromycin, rifabutin, ethambutol | 30 |
| MAC prevention | Clarithromycin, rifabutin | 30 |
| MAC prevention | Clarithromycin | 31 |
| MAC prevention | Rifabutin | 31 |
| MAC prevention | Azithromycin, rifabutin, fluconazole | 32 |
| Measles prevention | Vaccine | 45 |
| Measles prevention | Vaccine | 45 |
| Neurological problems | Nimodipine | 40 |
| Peripheral neuropathy treatment | Acupuncture, amitriptyline | 34 |
| Peripheral neuropathy treatment | Mexiletine | 34 |
| Pharmacokinetics | AZT, mexiletine | 40 |
| Pharmacokinetics | Oral ganciclovir | 40 |
| Pharmacokinetics | Itraconazole | 41 |
| Pharmacokinetics | Rifabutin, clarithromycin, azithromycin | 41 |
| Pharmacokinetics | Ciprofloxacin, rifampin | 42 |
| *Pneumocystis carinii* pneumonia (PCP) treatment | Atovaquone | 32 |
| PCP treatment | Trimetrexate | 32 |
| PCP prevention | Trimethoprim / sulfamethoxazole | 33 |
| PCP prevention | Pentamidine, dapsone | 33 |
| PCP prevention in children | Dapsone | 53 |
| PCP prevention in children | Pentamidine | 53 |
| Sinusitis treatment | Decongestants, nasal steroids, antibiotics | 42 |
| Stress management | Facilitated education groups | 46 |
| Stress management | Observational study | 46 |
| Syphilis treatment | Ceftriaxone | 34 |
| Syphilis treatment | Penicillin | 35 |
| Syphilis treatment | Penicillin | 35 |
| Taste comparison | Product 7068, Product 7068-LCT | 42 |
| Toxoplasmosis treatment | Azithromycin | 35 |
| Toxoplasmosis prevention | Pyrimethamine | 36 |

| Condition | Drug(s) | Page Number |
|---|---|---|
| Tuberculosis treatment | INH, rifampin, PZA, ethambutol, levofloxacin | 36 |
| Tuberculosis treatment | INH, rifampin, PZA, ethambutol | 37 |
| Tuberculosis prevention | INH | 37 |
| Tuberculosis prevention | Rifampin, PZA, INH | 39 |
| Wasting (weight loss) treatment | TPN with l-alanyl-glutamine dipeptide | 38 |
| Wasting (weight loss) treatment | Human growth hormone | 38 |
| Wasting (weight loss) treatment | MJ-7068 | 39 |
| Wasting (muscle wasting) treatment | Oxandrolone | 39 |
| Yeast infections in women (treatment) | Fluconazole | 48 |
| Yeast infections in women (prevention) | Fluconazole | 48 |
| Yeast infections in women (prevention) | Fluconazole | 48 |

# CD4 Cell (T-cell) Finder

## 100 CD4 cells (T-cells) or below:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 4 | AZT, ddC, ddI | 50 or below | HIV+ through AIDS | 12 |
| 23 | Oral ganciclovir | 50 or below without AIDS | HIV+ through AIDS | 20 |
| 23 | Oral ganciclovir | 100 or below with AIDS | HIV+ through AIDS | 20 |
| 22 | Oral ganciclovir | 100 or below | HIV+ through AIDS | 19 |
| 43 | TLC G-65 | 100 or below | AIDS | 29 |
| 47 | Clarithromycin, rifabutin | 100 or below | HIV+ through AIDS | 30 |
| 48 | Clarithromycin | 100 or below | HIV+ through AIDS | 31 |
| 50 | Azithro, rifabutin, fluconazole | 100 or below | HIV+ through AIDS | 32 |
| 73 | Itraconazole | 100 or below | AIDS | 41 |

## 200 CD4 cells (T-cells) or below:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 2 | AZT, ddC, ddI | below 200 or AIDS | HIV+ through AIDS | 11 |
| 8 | ddC | below 200 | HIV+, with symptoms, through AIDS | 13 |
| 9 | ddC | below 200 or AIDS or ARC | HIV+ through AIDS | 14 |
| 15 | Passive hyperimmune therapy | 50 to 200 | HIV+, with symptoms, through AIDS | 16 |
| 49 | Rifabutin | below 200 | HIV+ through AIDS | 31 |
| 53 | TMP / SMX | below 200 or past PCP | HIV+ through AIDS | 33 |
| 54 | Pentamidine, dapsone | below 200 or past PCP | HIV+ through AIDS | 33 |
| 61 | Pyrimethamine | below 200 | HIV+ through AIDS | 36 |
| 79 | Paromomycin | 150 or below | HIV+ through AIDS | 43 |

# CD4 Cell (T-cell) Finder

## 300 CD4 cells (T-cells) or below:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 7 | 3TC, AZT, ddC | 100 to 300 | HIV+ through AIDS | 13 |
| 11 | d4T | below 300 | HIV+ through AIDS | 14 |
| 12 | Procysteine | 50 to 300 | HIV+ through AIDS | 15 |
| 92 | Fluconazole | below 300 | HIV+ through AIDS (women only) | 48 |

## 500 CD4 cells (T-cells) or below:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 1 | AZT | 100 to 500 | HIV+ through AIDS | 11 |
| 6 | AZT, ddC, alpha interferon | 300 to 500 | HIV+, no AIDS | 13 |
| 10 | ddI, lentinan | 200 to 500 | HIV+ through AIDS | 14 |
| 13 | CD4-PE40 | 100 to 500 | HIV+ | 15 |
| 14 | Curdlan sulfate | below 500 | HIV+, ARC or AIDS | 16 |
| 16 | THF-gamma 2 | 100 to 500 | HIV+ through AIDS | 17 |
| 18 | gp120 (vaccine) | 50 to 500 | HIV+ through AIDS | 18 |
| 19 | gp160 (VAXSYN®) | 300 to 500 | HIV+, without symptoms | 18 |
| 86 | Facilitated education groups | 200 to 500 | HIV+ through AIDS | 46 |
| 102 | AZT, ddI | below 500 (older than 15 months) | HIV+, with symptoms, through AIDS | 52 |

## 1000 CD4 cells (T-cells) or below:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 102 | AZT, ddI | below 1000 (younger than 15 mo.) | HIV+, with symptoms, through AIDS | 52 |

## 100 CD4 cells (T-cells) or above:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 31 | 256U87, acyclovir | above 100, no upper limit | HIV+ through AIDS | 23 |

## 200 CD4 cells (T-cells) or above:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 98 | AZT | above 200, no upper limit | HIV+, without symptoms, no AIDS | 50 |

## 400 CD4 cells (T-cells) or above:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 95 | gp120 (vaccine) | above 400, no upper limit | HIV+, no symptoms (pregnant women) | 49 |

## 600 CD4 cells (T-cells) or above:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 17 | gp120 (vaccine) | above 600, no upper limit | HIV+, without symptoms, no AIDS | 17 |

# CD4 Cell (T-cell) Finder

## 2000 CD4 cells (T-cells) or above:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 100 | AZT | above 2000 (younger than 9 months) | HIV+, without symptoms | 51 |

## Antiretroviral studies with no CD4 (T-cell) Requirements:

| Trial # | Drug | CD4 cell (T-cell) count required | Stage of HIV disease | Page |
|---|---|---|---|---|
| 3 | Any anti-HIV drug | not specified | HIV+, without symptoms | 11 |
| 5 | AZT, ddI | not specified | Any, taking AZT at least one year | 12 |

## 1. HIV Infection: AZT

**Title:**

A Prospective Comparison of Zidovudine's Effects On CD4 Responses in HIV-Infected Caucasians, African-Americans and Latinos

**Purpose:**

To find out if AZT works differently in African Americans, Latinos and whites.

**About the study:**

Everyone in this study takes AZT capsules for six months. Blood tests are done every week for 3 months, and then once a month for three months.

**Required:**

- 100 to 500 CD4 cells (T-cells)
- at least 18 years old
- African-American, Caucasian, or Latino

**Not allowed:**

- anyone who has taken AZT or any other antiretroviral medicine before.

**Location:**

SFGH - AIDS Research Group
Carol Arri, RN
(415) 476-9296, Ext. 84094

If there are words or phrases in this book that you don't understand, you may be able to find explanations in the Glossary, starting on page 81.

## 2. HIV Infection: AZT, ddC, ddI

**Title:**

A Randomized, Comparative Trial of ZDV Versus ZDV Plus ddI Versus ZDV Plus ddC in HIV-Infected Patients (CPCRA 007)

**Purpose:**

To find out if it is better to take one antiretroviral drug or a combination of these drugs to treat HIV infection.

**About the Study:**

Patients are assigned by chance to one of three treatment groups. One group takes AZT by itself. Another group takes AZT and ddC. The third group takes AZT and ddI. Everyone in the study takes AZT, but neither patients nor their doctors know who is also taking ddC or ddI until the study ends. The study lasts for up to 2 1/2 years.

**Required:**

- HIV positive with CD4 cell (T-cell) count of 200 or below, or
- AIDS (no restriction on CD4 cell count)
- must take a drug to prevent PCP
- at least 13 years old

**Not allowed:**

- pancreatitis, peripheral neuropathy or AIDS dementia
- active opportunistic infection

**Location:**

Community Consortium. Ask your health care provider (see page 75).

Kaiser San Francisco
Allen Harris, RN,C
(415) 202-3481
(Kaiser health plan members only)

## 3. HIV Infection: ComPACT 1

**Title:**

A Randomized, Controlled Study to Help Determine When Persons with Asymptomatic HIV Disease Should Begin Anti-HIV Therapy (ComPACT 1)

**Purpose:**

To find out if it is better to take anti-HIV drugs early in the course of HIV infection, before people have any symptoms, or to wait to take them until symptoms of disease appear.

**About the study:**

Patients are assigned by chance to begin taking anti-HIV drugs right away, or to wait to begin taking them until they have definite symptoms of HIV disease. When patients start taking anti-HIV drugs, they may take any drug or combination of drugs they and their doctor think is best for them. The study may last as long as five years.

**Required:**

- HIV positive
- no symptoms of HIV disease
- not sure whether to start taking anti-HIV drugs
- have never taken an anti-HIV drug
- at least 13 years old

**Location:**

Community Consortium
Susan Sahl
(415) 476-7126
or ask your health care provider (see p. 75)

## 4. HIV Infection: AZT, ddC, ddI

**Title:**

A Randomized, Double-Blind, Three-Arm Study Comparing Combination to Monthly Alternating Nucleoside Therapy for the Treatment of Advanced HIV Disease (CD4 Less Than or Equal to 50 / mm$^3$) with a Prior History of Nucleoside Therapy (ACTG 193)

**Purpose:**

To compare the effectiveness of taking one anti-HIV drug or a combination of these drugs to treat HIV infection.

**About the study:**

Patients are assigned by chance to one of three treatment groups. One group takes both AZT and ddC every day. Another group takes both AZT and ddI every day. The third group switches treatment every month; first taking AZT by itself for one month, then ddI by itself for one month, then AZT again for one month, and so on. Neither the patients nor their doctors know which combination of drugs is being taken until the study ends.

**Required:**

- HIV positive, ARC or AIDS
- less than 50 CD4 cells (T-cells)
- at least 13 years old
- taking anti-HIV drugs for at least six months before starting the study
- must take a drug to prevent PCP

**Not allowed:**

- cancer which must be treated with chemotherapy
- severe peripheral neuropathy
- active opportunistic infection
- anyone who has ever had pancreatitis
- taking experimental anti-HIV drugs or immune boosting drugs within seven days before starting the study
- active alcohol or drug abuse

**Location:**

AIDS Community Research Consortium
Debbie Carroll
(415) 364-6563

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

SFGH - AIDS Research Group
Linda Johnson, RN
(415) 476-9296, Ext. 84099
Kathy Dybeck, RN
(415) 476-9296, Ext 84097

Stanford University Medical Center
ACTG Office
(415) 723-6231

UCSF - AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

## 5. HIV Infection: AZT, ddI

**Title:**

A Study to Evaluate the Short-Term Clinical and Virologic Significance of ZDV Resistance (ACTG 194)

**Purpose:**

To learn more about the effects of AZT-resistant strains of HIV on the immune system. To find out if people with AZT-resistant strains of HIV may be helped by taking ddI.

**About the study:**

Patients must have been taking at least 300 mg. of AZT per day for at least one year before starting the study. Patients are assigned by chance to continue taking AZT by itself, to switch to taking ddI by itself, or to take a combination of AZT and ddI. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts 16 weeks, with a possibility of a 16-week extension.

**Required:**

- HIV positive, ARC or AIDS
- taking at least 300 mg. of AZT for at least one year
- at least 12 years old

**Not allowed:**

- taking ddI or ddC for more than 30 days within the past year, or at any time within three months of starting this study
- pancreatitis, now or in the past
- peripheral neuropathy
- treatment for an acute illness. Treatment must have been completed for at least 14 days before starting the study.

**Location:**

AIDS Community Research Consortium
Debbie Carroll
(415) 364-6563

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

SFGH - AIDS Research Group
Nelson Murcar, RN
(415) 476-9296, Ext. 84092

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

Stanford University Medical Center
ACTG Office
(415) 723-6231

## 6. HIV Infection: AZT, ddC, Alpha Interferon

**Title:**

A Randomized Trial to Evaluate the Safety and Efficacy of Combination Therapy with Retrovir® and HIVID® Versus Retrovir®, HIVID® and Wellferon® for the Treatment of HIV Infection

**Purpose:**

To compare the effectiveness of two combinations of drugs for treatment of HIV infection. To learn if the drugs are safe to use in these combinations.

**About the study:**

All patients in this study take Retrovir® (AZT) capsules and HIVID® (ddC) capsules three times per day. In addition, one half of the patients are assigned by chance to also take Wellferon® (interferon alfa-nl) by injection into a muscle once per day. Patients learn to inject themselves so they may take the interferon at home. The study lasts 76 weeks.

**Required:**

- HIV positive
- 300 - 500 CD4 cells (T-cells)
- less than three months use of any other antiretroviral in the past
- at least 13 years old

**Not allowed:**

- AIDS
- use of any drugs intended to boost or decrease the function of the immune system (such as immunomodulators or corticosteroids)
- current substance abuse which would make it hard to follow the rules of the study
- peripheral neuropathy or heart disease
- radiation therapy or chemotherapy within four weeks of starting the study

**Location:**

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 7. HIV Infection: 3TC, AZT, ddC

**Title:**

A Randomized 3TC, ddC Double-Blind (ZDV Open-Labeled) Multicenter Trial to Evaluate the Safety and Efficacy of 3TC (low dose) Administered Concurrently with Zidovudine (ZDV, AZT) Versus 3TC (high dose) Administered Concurrently With ZDV Versus Dideoxycytidine (ddC) Administered Concurrently With ZDV in the Treatment of HIV-Infected Patients With a CD4 Cell Count Between 100 - 300 Cells / mm$^3$

**Purpose:**

To compare the effectiveness of the combination of AZT and 3TC to that of AZT and ddC for treatment of HIV infection. To compare the effectiveness of two doses of 3TC taken in combination with AZT. To learn more about the safety of taking these combinations of drugs.

**About the study:**

Everyone in this study takes AZT (also called zidovudine or ZDV). Patients are divided into three study groups. The first group takes AZT and a low dose of 3TC. The second group takes AZT and a high dose of 3TC. The third group takes AZT and ddC. Neither the patients nor their doctors know which combination of drugs is being taken until the study ends. All drugs are taken by mouth, two or three times per day. The study lasts 32 weeks. At the end of the study, patients may have the option to continue for 20 more weeks, for a total of one year.

**Required:**

- HIV positive, ARC or AIDS
- between 100 and 300 CD4 cells (T-cells)
- must have taken AZT for at least 24 weeks before starting the study
- at least 18 years old

**Not allowed:**

- unable to take AZT because of side effects
- peripheral neuropathy

**Location:**

ViRx, Inc.
Joyce Amann, CMA
Bridget Wagner, MD
(415) 474-2233

## 8. HIV Infection: ddC

**Title:**

A Treatment Protocol for the Use of Dideoxycytidine (ddC) in Patients with AIDS or Advanced ARC who Cannot be Maintained on Zidovudine (AZT) Therapy

**Purpose:**

To learn if the drug ddC is a safe and effective treatment for HIV disease for people who are not being helped by AZT, or who cannot take AZT due to side effects.

**About the study:**

Patients are assigned by chance to take one of two doses of ddC three times per day. Everyone knows what dose of ddC they are taking. The study lasts for an indefinite period.

**Required:**

- AIDS or HIV positive with symptoms of disease and less than 200 CD4 cells (T-cells)
- people whose HIV disease has gotten worse while they were taking AZT, or
- people who cannot take AZT due to side effects
- not eligible for other ddC studies
- at least 12 years old

**Not allowed:**

- anyone who has ever had peripheral neuropathy, regardless of the cause
- anyone who must take other drugs which could cause peripheral neuropathy, low white blood cell counts or kidney damage

**Location:**

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

## 9. HIV Infection: ddC

**Title:**

An Open-Label, Safety Study of Dideoxycytidine (ddC) in the Treatment of Patients with AIDS or Advanced ARC Who Cannot be Maintained on Zidovudine (ZDV) Therapy

**Purpose:**

To make the drug ddC available to people with AIDS or ARC who cannot take AZT or ddI, or whose health continues to get worse, despite treatment with AZT or ddI. To learn if ddC is a safe and effective treatment for these people.

**About the study:**

All patients in this program take ddC until the study ends (unspecified). ddC is taken in tablet form. Blood tests are done monthly.

**Required:**

- AIDS or advanced ARC or less than 200 CD4 cells (T-cells)
- cannot take AZT or ddI

**Not allowed:**

- past or current peripheral neuropathy

**Location:**

Any health care provider can enroll eligible patients into this program by calling Hoffman-La Roche at 1-800-332-21HIV (1-800-332-2144). Ask your provider for details.

## 10. HIV Infection: ddI, Lentinan

**Title:**

Phase I / II Study of the Efficacy of Combined Use of ddI and Lentinan in HIV Positive Patients

**Purpose:**

To find out if taking the drugs ddI and lentinan together works better than taking ddI alone as a treatment for HIV infection

**About the study:**

All patients take the same dose of ddI by mouth twice per day throughout the course of the study. ddI is taken by itself for the first six weeks. Patients are then assigned by chance to also take lentinan or a placebo, given by IV infusion once per week. Patients who have already been taking ddI alone for at least six weeks before they begin the study will enter the infusion phase immediately. The study lasts six to twelve months.

**Required:**

- HIV positive
- CD4 cell (T-cell) count between 200 and 500
- 18 to 60 years old

**Not allowed:**

- active opportunistic infections
- use of ddI for more than 3 months before starting the study
- active injection drug use
- pancreatitis, peripheral neuropathy or Kaposi's sarcoma

**Location:**

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 11. HIV Infection: d4T

**Title:**

A Randomized, Blinded Evaluation of Two Doses of Stavudine (d4T) to Make Treatment Available to Severely Immunocompromised Patients with HIV Infection Who Have Failed or Are Intolerant of Alternative Antiretroviral Therapy (d4T Parallel Track Program)

**Purpose:**

To make d4T available to patients with HIV who cannot take AZT or ddI because of side effects, or whose HIV disease is getting worse while they are taking these drugs. To find out more about the safety of d4T and how well it works as a treatment for HIV infection.

**About the study:**

This is an expanded access program for d4T. All patients in this study take one of two doses of d4T twice per day. The safety and effectiveness of the two doses will be compared.

**Required:**

- HIV positive, ARC or AIDS
- less than 300 CD4 cells (T-cells)
- unable to take AZT or ddI because of side effects, *or*
- HIV disease is getting worse while taking AZT or ddI
- at least 13 years old

**Not allowed:**

- anyone with peripheral neuropathy
- anyone who has cancer that needs to be treated with chemotherapy

**Location:**

Any health care provider can enroll eligible patients into this program by calling Bristol-Myers Squibb at 1-800-842-8036. Ask your health care provider for details.

## 12. HIV Infection: Procysteine

**Title:**

A Double-Blind Randomized Parallel Group Study Comparing Procysteine™ to Placebo in HIV-Infected Patients Who Are Taking Antiretroviral Nucleosides

**Purpose:**

To find out if taking a drug called Procysteine™ along with other anti-HIV drugs is helpful for treating HIV infection.

**About the study:**

Everyone in this study takes one or more of the anti-HIV drugs AZT, ddI or ddC. In addition, patients are assigned by chance to take Procysteine™ or a placebo. Neither the patients nor their doctors know if the patient is taking Procysteine™ until the study ends. All drugs are taken by mouth. The study lasts about one year.

**Required:**

- HIV positive, ARC or AIDS
- patients with ARC or AIDS must have a CD4 cell (T-cell) count between 50 - 300
- patients with no symptoms of HIV disease must have a CD4 cell (T-cell) count between 50 - 200
- taking AZT, ddI, ddC or a combination of these drugs for at least three months before starting the study
- at least 18 years old

**Not allowed:**

- active opportunistic infection
- active substance abuse
- cancer that must be treated with chemotherapy
- taking EPO, G-CSF or GM-CSF within 28 days of starting the study

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

Santa Clara County Early Intervention Program
Debbie Carroll, RN
(415) 364-6563

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 13. HIV Infection: CD4-PE40

**Title:**

Safety, Tolerance, Efficacy and Pharmacokinetics of Multiple Doses of CD4-PE40 in the Treatment of HIV Infected Individuals

**Purpose:**

To find out if it is safe for people with HIV infection to take CD4-PE40. To study the effects of CD4-PE40 on the immune system. To learn how CD4-PE40 is absorbed and processed by the body.

**About the study:**

All patients in this study take CD4-PE40, by infusion into a vein. This is a dose escalation study. This means that the first group of patients who enter the study are treated with a low dose of the drug. If there are no severe side effects at the low dose level, the next group begins the study at a higher dose level. This continues until the highest dose level has been reached. The study lasts 13 weeks.

**Required:**

- HIV positive
- no other anti-HIV drugs within two months before starting the study
- CD4 cell (T-cell) counts between 100 and 500
- at least 18 years old

**Not allowed:**

- taking any drugs intended to increase or decrease the function of the immune system within 60 days before starting the study
- active substance abuse
- most types of cancers

**Location:**

Stanford University Medical Center
ACTG Office
(415) 723-6231

## 14. HIV Infection: Curdlan Sulfate

**Title:**

Phase I / II Study of Curdlan Sulfate

**Purpose:**

To find out if it is safe for people with HIV infection to take curdlan sulfate. To learn how curdlan sulfate is absorbed and processed by the body.

**About the study:**

All patients in this study take curdlan sulfate, given by infusion into a vein. This is a dose escalation study. This means that the first group of patients who enter the study are treated with a low dose of the drug. If there are no severe side effects at the low dose level, the next group begins the study at a higher dose level. This continues until the highest dose level has been reached. There are two treatment phases. Patients in the first phase are given a single infusion, and must stay in the hospital for 24 hours. Patients in the second phase are given one infusion per day for seven days, and must stay in the hospital for 48 hours. Patients may participate in both treatment groups.

**Required:**

- HIV positive, ARC or AIDS
- between 18 and 60 years old
- CD4 cell (T-cell) count below 500
- platelet count above 100,000

**Not allowed:**

- active opportunistic infection
- Kaposi's sarcoma
- allergy to heparin
- taking experimental drugs within one month before starting the study
- taking any drugs intended to decrease the function of the immune system within one month before starting the study
- active injection drug use

**Location:**

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 15. HIV Infection: Passive Hyperimmune Therapy (ImmuPath)

**Title:**

Passive Hyperimmune Therapy in the Treatment of AIDS: Phase III Treatment IND Protocol

**Purpose:**

To find out if passive hyperimmune therapy (ImmuPath) is a safe and effective treatment for HIV disease.

**About the study:**

ImmuPath is HIV positive hyperimmune plasma, an extract from human blood containing very high levels of antibodies to HIV. Patients are assigned by chance to receive ImmuPath or placebo, given by injection into a vein once or twice per month. Neither the patients nor their doctors know which is being given until the study ends. The study lasts two years. There is also an open-label arm of the study for people with between 200 and 400 CD4 cells (T-cells), to find out if ImmuPath is helpful for people in earlier stages of HIV disease.

**Required:**

- AIDS, ARC or HIV positive with symptoms of disease
- CD4 cell (T-cell) count between 50 and 200
- must be taking AZT, ddC or ddI
- must be taking a drug to prevent PCP
- at least 18 years old

**Not allowed:**

- active toxoplasmosis or MAC infection
- lymphoma
- taking chemotherapy for Kaposi's sarcoma
- taking any drug intended to increase the function of the immune system
- anyone receiving TPN

*Note:* Plasma donors are also needed. Plasma donors must meet the following requirements:

**Required for plasma donors:**

- more than 400 CD4 cells (T-cells)
- never had an an opportunistic infection
- high level of p24 antibodies
- not taking any other experimental drugs

**Location:**

HemaCare Corporation
David Sexton, RN
(415) 399-0971

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You may not be sure just what a clinical trial is. Or, even if you want to join a trial, you may not know how. See pages 57 through 61 for answers to a few of the most commonly asked questions about what a clinical trial is, and how you can join a trial.

## 16. HIV Infection: THF-gamma 2

**Title:**

Phase I Study of THF-gamma 2 at Doses of 100 and 200 ng/kg in AZT-Treated, HIV-Positive Patients

**Purpose:**

To find out if it is safe for people with HIV infection to take THF-gamma 2. To compare the safety of two different dose levels of THF-gamma 2.

**About the study:**

All patients in this study take THF-gamma 2. The drug is injected into a muscle once per day for 15 days, followed by a six-day "wash-out" period during which no drug is given. A total of four 15-day cycles of injections are given, all separated by six-day wash-out periods. This is a dose escalation study. This means that the first group of patients takes a low dose level of the drug. If there are no serious side effects at the low dose level, the next group of patients takes a higher dose level. The treatment part of the study lasts 12 weeks, with two more months of follow-up.

**Required:**

- HIV positive, ARC or AIDS
- CD4 cell (T-cell) count between 100 and 500
- taking 500 mg. of AZT for at least six weeks before starting the study
- at least 18 years old

**Not allowed:**

- active opportunistic infection
- any cancer except Kaposi's sarcoma
- taking other experimental drugs within four weeks before starting the study
- cancer chemotherapy or radiation therapy within four weeks before starting the study
- hemophilia
- active substance abuse

**Location:**

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 17. HIV Infection: Vaccine Trial

**Title:**

A Phase II Multicenter Study of the Safety and Efficacy of MN rgp120/HIV-1 Vaccine Compared with Placebo in HIV-1 Seropositive Subjects with CD4 Cell Counts Greater Than 600 Cells / mm$^3$ (Protocol V0346g)

**Purpose:**

To find out if it is safe to give MN rgp120/HIV-1 (an experimental vaccine treatment for HIV infection) to people with HIV infection. To learn if giving this experimental vaccine to people with HIV infection may help prevent further damage to the immune system and help prevent symptoms of disease.

**About the study:**

Patients are assigned by chance to receive an experimental vaccine or a placebo. Neither the patients nor their doctors know which is being taken until the study ends. The vaccine or placebo is given by injection into a muscle. Injections are given monthly for six months, then every two months for 30 more months. The study lasts three years.

**Required:**

- HIV positive, without symptoms of disease
- in good general health
- more than 600 CD4 cells (T-cells)

**Not allowed:**

- AIDS
- current or past use of AZT or any other anti-HIV drug
- taking any experimental drugs
- taking drugs to prevent PCP
- taking corticosteroids or any other drugs intended to decrease the function of the immune system within 30 days before starting the study
- anyone who has received another experimental HIV vaccine

**Location:**

Marcus A. Conant, MD Clinical Research
Steven Ellis, RN
Joanna Van Elk
(415) 923-0222

SFGH - AIDS Research Group
Mary Payne, RN
(415) 476-9296, Ext. 84602

## 18. HIV Infection: Vaccine Trial

**Title:**

A Phase I Trial of gp120 Vaccine Therapy of HIV-1 Infected Individuals with 50 - 500 cells / mm³ (ACTG 209)

**Purpose:**

To find out if it is safe for people with HIV infection to take an experimental vaccine made from gp120. To learn about the effects of this vaccine on the immune system. To find out if gp120 vaccine can help prevent people with HIV infection from developing symptoms of disease.

**About the study:**

Patients are assigned to one of four study groups, on the basis of their CD4 cell (T-cell) counts. Three of these groups must already be taking AZT before starting the study, and will continue to take AZT as long as they are in the study. One of the groups receives only a series of injections of the vaccine. The other three groups take AZT and are assigned by chance to also receive injections of vaccine or placebo injections. Neither the patients nor their doctors know which is being given until the study ends. The study lasts seven months.

**Required:**

- HIV positive
- CD4 cell (T-cell) count between 50 and 500
- at least 13 years old
- three of the study groups must have taken at least 500 mg. of AZT per day for between two and twelve months before starting the study

**Not allowed:**

- taking ddC or ddI
- taking any drug intended to lower the function of the immune system
- taking interferon
- taking any other experimental drugs
- taking AZT for less than two or more than twelve months before starting the study

**Location:**

SFGH - AIDS Research Group
David Gary, RN
(415) 476-9296, Ext. 94095

Stanford University Medical Center
ACTG Office
(415) 723-6231

## 19. HIV Infection: Vaccine Trial

**Title:**

A Study of the Effect of VAXSYN® on Detection and Quantitation of Virus in Asymptomatic HIV Infected Patients

**Purpose:**

To learn if VAXSYN® (an experimental gp160 vaccine for HIV) is safe to give to people with HIV infection. To learn if VAXSYN® injections may help prevent people with HIV infection from getting symptoms of disease.

**About the study:**

Patients are assigned by chance to receive VAXSYN® injections or AZT pills. Those assigned to VAXSYN® are given seven injections into a muscle during a one-year period. Those assigned to AZT take 600 mg. per day for one year. The study lasts one year.

**Required:**

- HIV positive, but without symptoms of HIV disease
- 300 - 500 CD4 cells (T-cells)
- 18 - 60 years old

**Not allowed:**

- use of antiretroviral drugs (such as AZT, ddI or ddC) for more than one month during the past year
- current use of any other experimental treatment for HIV disease
- current alcohol or drug abuse
- liver or kidney disease

**Location:**

Stanford University Medical Center
Pat Cain, RN
(415) 723-8292

## 20. CMV Retinitis Retreatment: Ganciclovir, Foscarnet

**Title:**

CMV Retinitis Retreatment Trial (CRRT) Protocol

**Purpose:**

CMV retinitis sometimes keeps getting worse even while it is being treated, or comes back after treatment is finished. The purpose of this study is to compare the safety and effectiveness of three ways of treating CMV retinitis if it keeps getting worse or comes back after treatment.

**About the study:**

Patients are assigned by chance to one of three treatment arms, using different doses and combinations of ganciclovir and foscarnet. Both drugs are given by infusion into a vein. If treatment causes the white blood cell count to fall too low, patients are given G-CSF to help boost the white blood cell count. Patients are in this study for an indefinite length of time.

**Required:**

- AIDS
- CMV retinitis in one or both eyes
- already treated with ganciclovir or foscarnet for at least 28 days
- at least 18 years old

**Not allowed:**

- having taken a combination of ganciclovir and foscarnet in the past
- active substance abuse that would interfere with following the rules of the study
- retinal detachment, unless it is scheduled to be repaired

**Location:**

SFGH - AIDS Research Group
Ted Bush, RN
(415) 476-9296, Ext. 84098

## 21. CMV Retinitis Maintenance Treatment: Oral Ganciclovir

**Title:**

A Randomized Study Comparing the Safety and Efficacy of Two Regimens of Oral Ganciclovir to Intravenous Ganciclovir Maintenance Therapy for Cytomegalovirus Retinitis in People with AIDS Who Have Received Prior Ganciclovir Therapy (ICM 1774)

**Purpose:**

To learn if taking ganciclovir capsules is as effective as taking ganciclovir by intravenous infusion for long-term maintenance treatment of CMV retinitis.

**About the study:**

In order to be eligible to join this study, patients must have already been enrolled in Syntex 1654, another oral ganciclovir study. In this study, patients are assigned by chance to take either intravenous or oral ganciclovir for 20 weeks. After 20 weeks all patients are allowed to take oral ganciclovir for 32 weeks if they wish.

**Required:**

- HIV positive
- at least 13 years old
- CMV retinitis diagnosed while on Syntex 1654
- CMV retinitis must have been treated for at leas four weeks with ganciclovir and must be stable now

**Not allowed:**

- CMV retinitis which was diagnosed more than four months ago
- persistent diarrhea, nausea or abdominal pain
- very low white blood cell counts

**Location:**

East Bay AIDS Center
Carole Ferrell, RN
(510) 204-1870

Many women think they can't join clinical trials. In fact, most trials are open to both men *and* women. There are also a few trials for women only. If you are a woman you may want to turn to page 63 for special information about women and clinical trials.

## 22. CMV Disease Prevention: Oral Ganciclovir

**Title:**

A Randomized, Comparative, Placebo-Controlled Trial of the Safety and Efficacy of Oral Ganciclovir For Prophylaxis of Cytomegalovirus (CMV) Retinal and Gastrointestinal Mucosal Disease in HIV-Infected Individuals with Severe Immunosuppression (CPCRA 023)

**Purpose:**

To find out if taking ganciclovir pills can help prevent people who have both HIV and CMV infections from getting symptoms of CMV disease.

**About the study:**

Patients are assigned by chance to take ganciclovir pills or placebo. Neither the patients nor their doctors know which is being taken until the study ends. The study may last up to two years.

**Required:**

- HIV positive
- CD4 cell (T-cell) count of 100 or below
- positive test for CMV
- at least 13 years old

**Not allowed:**

- anyone who has ever had active CMV disease
- taking any other medicine which acts against CMV
- lymphoma
- taking cancer chemotherapy

**Location:**

Community Consortium. Ask your health care provider (see page 75).

## 23. CMV Disease Prevention: Oral Ganciclovir

**Title:**

A Randomized Double-Blind Study of the Efficacy and Safety of Oral Ganciclovir for the Prevention of CMV Disease in People Infected with the Human Immunodeficiency Virus (Syntex 1654)

**Purpose:**

To find out if taking ganciclovir pills can help prevent people with HIV infection from getting CMV disease.

**About the study:**

Patients are assigned by chance to take ganciclovir pills or a placebo. Neither the patients nor their doctors know which is being taken until the study ends. Pills are taken three times per day. The study lasts at least 18 months.

**Required:**

- HIV positive, ARC or AIDS
- patients who do not have AIDS must have a CD4 cell (T-cell) count below 50
- patients who have AIDS must have a CD4 cell (T-cell) count below 100
- laboratory evidence of CMV infection, but *without* CMV disease
- at least 13 years old

**Not allowed:**

- past or present CMV disease
- use of any drug which acts against CMV within 60 days before starting the study
- gastrointestinal symptoms (such as nausea, abdominal pain or diarrhea) that are not helped by taking medicine
- very low white blood cell count

**Location:**

Davies HIV Institute
Ann Conroy, RN
(415) 565-6649

East Bay AIDS Center
Carole Ferrell, RN
(510) 204-1291

Mt. Zion HIV Clinical Research Center
John Sayre, RN
(415) 476-6356

San Francisco VA Medical Center
Manon Marovich, RN
(415) 221-4810, Ext. 3944

## 24. CMV Disease Prevention: HPMPC

**Title:**

A Phase I / II Study of the Safety, Tolerance and Pharmacokinetics of (S)-IL3 Hydroxy-2-(Phosphonylmethoxy) Propyl] Cytosine (HPMPC) in HIV-Infected Patients with Asymptomatic Cytomegalovirus Infection

**Purpose:**

To learn if it is safe to give HPMPC by infusion into a vein. To learn how HPMPC is absorbed and processed by the body. To learn if HPMPC may help prevent symptoms of cytomegalovirus (CMV) disease in people who are infected with CMV.

**About the study:**

All patients in this study receive HPMPC. This is a dose escalation study. This means that the first group of patients who enter the study are treated with a low dose of the drug. After the first group finishes treatment at the low dose level, the next group begins the study at a higher dose level. This continues until the highest dose level has been reached. HPMPC is given by infusion into a vein once per week. Two overnight stays in the hospital are required. The study lasts one month. Patients who are able to take the drug without side effects may continue on maintenance HPMPC therapy after the study ends.

**Required:**

- HIV positive
- positive culture for CMV in urine or semen
- age 18 - 60

**Not allowed:**

- active CMV disease in the eyes, lungs, esophagus, stomach or colon
- other active opportunistic infection
- heart, liver or kidney disease
- treatment with ganciclovir or foscarnet
- current treatment with certain other drugs; including ddI, acyclovir, amphotericin B, fluconazole, diuretics and certain antibiotics
- active substance abuse

**Location:**

Mt. Zion HIV Clinical Research Center
Eileen Glutzer, RN
(415) 476-6356

SFGH - AIDS Research Group
Ted Bush, RN
(415) 476-9296, Ext. 84098

There are many organizations that can help you learn more about HIV disease and about treatments for HIV disease. You may want to read the Resources section starting on page 77 for more information on these groups.

## 25. Cryptococcal Meningitis Treatment: Macrophage-Colony Stimulating Factor (M-CSF)

**Title:**

Safety and Efficacy of Macrophage-Colony Stimulating Factor in AIDS Patients with Cryptococcal Meningitis

**Purpose:**

To find out if it is safe for patients with HIV to take macrophage-colony stimulating factor (M-CSF) with amphotericin B or fluconazole for treatment of cryptococcal meningitis. To find out if it is safe for patients to take M-CSF with anti-HIV drugs such as AZT, ddC or ddI.

**About the study:**

All patients in this study take amphotericin B or fluconazole for treatment of their cryptococcal meningitis. In addition, all patients also take (M-CSF). Patients must stay in the hospital for at least the first five days of the study. Then, if there are no serious problems with the medicines, they may complete their treatment at home. Daily visits to the clinic are required for the first four weeks of outpatient treatment. The study lasts ten weeks.

**Required:**

- AIDS
- cryptococcal meningitis
- must be taking FDA-approved anti-HIV drugs
- at least 18 years old

**Not allowed:**

- taking experimental anti-HIV drugs
- taking drugs intended to boost the function of the immune system
- taking amphotericin B or fluconazole to treat any disease other than cryptococcal meningitis within 30 days before starting the study
- cancer chemotherapy or radiation therapy within 30 days before starting the study
- active opportunistic infection other than cryptococcal meningitis
- active injection drug use

**Location:**

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, Ext. 3763

## 26. Cryptococcal Meningitis Treatment: Amphotericin B, Flucytosine, Fluconazole, Itraconazole

**Title:**

A Randomized Double Blind Protocol Comparing Amphotericin B with Flucytosine to Amphotericin B Alone Followed by a Comparison of Fluconazole and Itraconazole in the Treatment of Acute Cryptococcal Meningitis (ACTG 159 / MSG Study 17)

**Purpose:**

To learn which combination of these drugs works best for treating cryptococcal meningitis. To learn more about the safety of these combinations of drugs

**About the study:**

Patients are assigned by chance to take amphotericin B alone or in combination with flucytosine for 14 days. Patients must stay in the hospital for this part of the study. After this, patients are assigned by chance to take either fluconazole or itraconazole for eight weeks. These drugs are taken by mouth, so patients who are well enough may be released from the hospital. Neither patients nor their doctors know which drug is being taken until the study ends. Patients may need to have at least one lumbar puncture ("spinal tap") while on the study. The study lasts ten weeks.

**Required:**

- HIV positive
- first episode of acute cryptococcal meningitis
- at least 13 years old

**Not allowed:**

- active hepatitis
- treatment for more than 72 hours within the past seven days with any of the above drugs
- other central nervous system disease
- patients who have to take histamine blockers or antacids all the time

**Location:**

Kaiser San Francisco
Isabel Gaitan, RN
(415) 202-3486
(Kaiser health plan members only)

SFGH - AIDS Research Group
David Gary, RN
(415) 476-9296, Ext. 84095

Santa Clara Valley Medical Center
Paul DelSecco, RN
(408) 299-5523

## 27. Cryptococcal Meningitis Treatment (Prevention of Relapse): Itraconazole, Fluconazole

**Title:**

Double-Blind, Randomized, Comparative Study of Itraconazole and Fluconazole as Maintenance Therapy for Preventing Relapse of AIDS-Related Cryptococcal Meningitis

**Purpose:**

To find out if taking the drugs itraconazole or fluconazole can help prevent people who have been treated for cryptococcal meningitis from getting the disease again.

**About the study:**

Patients are assigned by chance to take itraconazole pills or fluconazole pills once daily for one year. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts one year.

**Required:**

- AIDS-related cryptococcal meningitis, successfully treated, within four months of study entry
- at least 13 years old

**Not allowed:**

- use of any experimental drug (except itraconazole) within one month of starting study. For purposes of this study, drugs available under an FDA-authorized expanded access program are not considered experimental.
- treatment with amphotericin B injected into the central nervous system
- patients who require histamine blockers or continual antacid use
- taking rifampin, phenytoin, phenobarbital or carbamazepine

**Location:**

Kaiser San Francisco
Gretchen Van Raalte, RN
(415) 202-3482
(Kaiser health plan members only)

SFGH - AIDS Research Group
David Gary, RN
(415) 476-9296, Ext. 84095

St. Francis HIVCare
Drew Catapano
(415) 353-6215

## 28. Herpes Treatment: SP-303T

**Title:**

A Pilot Study to Determine the Safety and Efficacy of Topically Applied SP-303T in Patients with AIDS and HSV Infection Unresponsive to Acyclovir

**Purpose:**

To learn if SP-303T is effective in treating herpes outbreaks in people for whom acyclovir does not work well.

**About the study:**

All patients in this study apply SP-303T cream to their herpes outbreaks three times per day. The study lasts from 10 to 42 days.

**Required:**

- AIDS
- herpes outbreak which has lasted more than 30 days, and which has not been helped by taking acyclovir
- at least 18 years old

**Not allowed:**

- allergy to citrus fruits, black currant berries or rose hips
- taking other experimental drugs
- using other treatments for herpes while in this study

**Location:**

SFGH - Infectious Diseases Division
Rowena Mah, RN
(415) 476-9296, Ext. 84093

## 29. Herpes Treatment: 256U87

**Title:**

A Randomized, Double-Blind, Controlled Trial to Investigate the Efficacy and Safety of Orally Administered 256U87 in the Treatment of Recurrent Genital Herpes Infections in HIV Positive Patients

**Purpose:**

To compare the effectiveness of 256U87 to acyclovir for treating recurrent genital herpes.

**About the study:**

Patients are assigned by chance to take 256U87 pills or acyclovir pills for five days. Neither the patients nor their doctors know which is being taken until the study ends. The study requires a minimum of six clinic visits. Patients who complete all visits are paid $100.

**Required:**

- HIV positive
- genital herpes that keeps coming back
- two or more outbreaks within the past 6 months
- at least 18 years old

**Not allowed:**

- taking steroids or any systemic treatment for herpes
- liver or kidney problems

**Location:**

SFGH - Infectious Diseases Division
Patricia Duff, RN, NP
(415) 431-0790

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 30. Herpes Treatment: Trifluridine

**Title:**

A Phase II Open-Label Study for the Treatment of Acyclovir-Resistant Mucocutaneous Herpes Simplex Disease with Topical Trifluridine in Patients with AIDS (ACTG 172)

**Purpose:**

To learn if trifluridine liquid is safe and effective for treating herpes simplex outbreaks that do not get better with the standard treatment, acyclovir.

**About the study:**

Patients in this study apply trifluridine liquid to their herpes outbreak three times per day. A doctor or nurse examines the herpes outbreak once each week to see if it's getting better. The study lasts between 10 and 42 days.

**Required:**

- HIV positive, ARC or AIDS
- herpes simplex infection of the skin or mucous membranes, that has not gotten better after using acyclovir
- at least 13 years old

**Not allowed:**

- use of any other drugs which may act against herpes
- use of any drugs intended to increase or decrease the function of the immune system (such as immunomodulators or corticosteroids)

**Location:**

SFGH - Clinical Research Section
Rowena Mah, RN
(415) 476-9296, Ext. 84093

## 31. Herpes Prevention: 256U87, Acyclovir

**Title:**

A Comparative Trial of 256U87 and Acyclovir for the Suppression of Ano-Genital Herpes Infections in HIV-Infected Patients

**Purpose:**

To compare 256U87 to acyclovir for long-term prevention of herpes outbreaks. To compare the effectiveness of taking 1000 mg. of 256U87 once per day to taking 500 mg. of 256U87 twice per day. To learn if it is safe to take 256U87 every day for a long period of time.

**About the study:**

Patients are assigned by chance to one of three study groups. One group takes 256U87 pills at a dose of 500 mg. twice per day. Another group takes 256U87 pills at a dose of 1000 mg. once per day. The third group takes acyclovir pills at a dose of 400 mg. twice per day. Neither patients nor their doctors know which is being taken until the study ends. The study lasts one year.

**Required:**

- HIV positive
- at least 100 CD4 cells (T-cells)
- genital or anal herpes that keeps coming back
- at least 18 years old

**Not allowed:**

- liver or kidney disease
- use of other drugs with activity against herpes
- use of interferon

**Location:**

Marcus A. Conant, MD Clinical Research
Christopher Oligney, PA-C
(415) 661-2613

Summit Medical Center
Adult Immunology Clinic
Jamie Carroll, RN
(510) 273-8200

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

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If you are between the ages of 13 and 18 you may not be sure where you "fit in" with clinical trials. You may be eligible for trials designed for either children or adults. If you are interested in joining a trial, special health care and support programs for youth can help you sort through the confusion. Pages 67 and 68 will help you get started.

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## 32. Herpes Zoster Treatment: 882C87, Acyclovir

**Title:**

A Double-Blind, Multicenter Study Comparing Oral 882C87 with Oral Acyclovir for Treatment of Localized Herpes Zoster in Immunocompromised Patients

**Purpose:**

To compare the safety and effectiveness of 882C87 and acyclovir for treating an outbreak of herpes zoster ("shingles").

**About the study:**

Patients are assigned by chance to take 882C87 pills twice per day for 14 days or acyclovir pills five times per day for 14 days. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts six months.

**Required:**

- HIV negative, HIV positive, ARC or AIDS
- localized (confined to one area of the body) herpes zoster
- must begin the study within 72 hours of when the outbreak appeared
- loss of immune function due to HIV disease, chemotherapy, radiation therapy, organ transplant or certain other causes
- at least 18 years old

**Not allowed:**

- disseminated (covering more than one area of the body) herpes zoster
- prior outbreak of herpes zoster within the past three months
- prior outbreak of herpes zoster that was not helped by taking acyclovir
- taking other drugs which act against herpes infections
- active drug or alcohol abuse within the past six months

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

## 33. Herpes Zoster Treatment: BV-ara-U or Acyclovir

**Title:**

Evaluation of SQ 32,756 (BV-ara-U) vs. Acyclovir in the Treatment of Localized Herpes Zoster in Immunocompromised Patients (ACTG 169)

**Purpose:**

To compare the effectiveness of BV-ara-U to acyclovir for treatment of localized herpes zoster ("shingles") in people with HIV infection.

**About the study:**

Patients are assigned by chance to take BV-ara-U pills once daily for 10 days or acyclovir pills five times daily for 10 days. Neither the patients nor their doctors know which is being used until the study ends. Patients come to the clinic every day during the 10-day treatment period. They return weekly for follow-up for three weeks, then monthly for 11 months. Total length of time on the study is one year.

**Required:**

- HIV positive
- at least 18 years old
- localized herpes zoster
- entered into the study within 72 hours of when the herpes sores first appear

**Not allowed:**

- treatment with ganciclovir, foscarnet or any other antiviral except AZT or ddI within two weeks of starting study
- widespread herpes zoster
- treatment with any immune globulin within two weeks of starting study
- use of certain other drugs, including cimetidine, heparin, interferon, probenecid or cortisone

**Location:**

Summit Medical Center
Adult Immunology Clinic
Jamie Carroll, RN
(510) 273-8200

Mt. Zion HIV Clinical Research Center
Ron Loya, PA-C
(415) 476-6356

**You may have heard that injection drug users can't be in clinical trials. The truth is, injection drug users are *not* always excluded from joining a clinical trial. See page 69 for more information about injection drug users and clinical trials.**

## 34. Oral Kaposi's Sarcoma Treatment: Velban Injections

**Title:**

Intralesional Velban For Oral KS

**Purpose:**

To find out if it is safe to inject Velban into KS lesions in the mouth. To find out if injecting Velban into the lesions may make them smaller or make them go away.

**About the study:**

Marker KS lesions ("indicator" lesions) are selected and measured, and photographs may be taken. Some of these lesions are injected, and others are used as "controls." Lesions are measured several times after treatment to see if they change in size. The study lasts two to three months.

**Required:**

- AIDS, with KS in the mouth
- fewer than 50 lesions

**Not allowed:**

- injections of other drugs into the same "indicator" lesions in the past

**Location:**

UCSF - AIDS Clinic
Cecily Cosby, NP
(415) 476-3226

**If there are words or phrases in this book that you don't understand, you may be able to find explanations in the Glossary, starting on page 81.**

## 35. Kaposi's Sarcoma Treatment: CD8 Expansion Plus IL-2

**Title:**

Phase II Study of Autologous Activated CD8(+) T-Cells Expanded *In Vitro* and Infused with Five Days of Recombinant Interleukin-2 Into Patients with AIDS-Related Kaposi's Sarcoma

**Purpose:**

To find out if giving activated CD8 cells and interleukin-2 (IL-2) is helpful in treating Kaposi's sarcoma (KS) in people with AIDS.

**About the study:**

A CD8 cell is a type of white blood cell, and is an important part of the immune system. IL-2 is a substance which can boost the function of certain cells of the immune system. In this study, CD8 cells are removed from the body, grown in a laboratory for 10 to 18 days, and put back into the body by infusion into a vein. At the same time, and once per day for four more days, IL-2 is given, also by infusion into a vein. This treatment is repeated once each month until five treatment cycles have been given. Including a ten week follow-up period, the study lasts about six months. If the treatment seems to be helping, patients may be allowed to repeat the five cycles of treatment.

**Required:**

- AIDS
- at least one KS lesion which has not had local treatment before (local treatment means injecting a drug directly into the lesion)
- taking an approved anti-HIV drug (such as AZT, ddC or ddI) for at least eight weeks before starting the study
- between 18 and 55 years old

**Not allowed:**

- KS in the lungs
- active infection (CMV or MAC may be allowed)
- any other type of cancer
- any bleeding disorder
- may not have chemotherapy or radiation therapy for at least 30 days before entering the study
- active substance abuse

**Location:**

SFGH - AIDS Research Group
Carol Arri, RN
(415) 476-9296, Ext 84094

## 36. Kaposi's Sarcoma Treatment: Chemotherapy, ddC, ddI

**Title:**

Phase I / II Study of Combination Chemotherapy (Adriamycin, Bleomycin, +/- Vincristine) and Dideoxyinosine( ddI) or Dideoxycytidine (ddC) in the Treatment of AIDS-Related Kaposi's Sarcoma (ACTG 163)

**Purpose:**

To find out if it is safe for people with AIDS and Kaposi's sarcoma (KS) to take a combination of anti-cancer drugs along with a single anti-HIV drug (either ddC or ddI). To find out how well these combinations of anti-cancer and anti-HIV drugs work in treating Kaposi's sarcoma.

**About the study:**

All patients in this study take a combination of the anti-cancer drugs adriamycin, bleomycin and vincristine (ABV), given by infusion into a vein once every two weeks. ABV treatment is given for between 12 and 44 weeks, depending on side effects and response to treatment. In addition, patients are assigned by chance to also take an anti-HIV drug, either ddC or ddI. ddC or ddI are taken by mouth two or three times per day during the time that ABV treatments are being given, and for 24 weeks after the last ABV treatment. The study lasts between 36 and 68 weeks.

**Required:**

- AIDS
- Kaposi's sarcoma. Patients must have at least one of the following: more than 25 KS lesions of the skin or mucous membranes, KS involving internal organs, or fluid retention and swelling caused by KS.
- at least 12 years old

**Not allowed:**

- taking other anti-KS drugs within seven days before starting the study
- taking experimental drugs within 14 days before starting the study
- taking antibiotics which cause a decrease in red blood cell counts
- peripheral neuropathy, pancreatitis, diarrhea or seizures
- anyone who has taken adriamycin, bleomycin or vincristine in the past
- most other types of cancers

**Location:**

SFGH - AIDS Research Group
Carol Arri, RN
(415) 476-9296, Ext 84094

## 37. Kaposi's Sarcoma Treatment: Alpha Interferon, ddI

**Title:**

Open-Label, Phase II Study with Randomization to One of Two Doses of IFN-2b Combined with ddI Daily

**Purpose:**

To find out if it is safe for people with Kaposi's sarcoma to take a combination of the drugs alpha interferon and ddI. To find out if taking this combination of drugs is helpful in treating Kaposi's sarcoma. To learn about the effects of this combination of drugs on the immune system.

**About the study:**

Everyone in this study takes the same dose of ddI twice per day. In addition, patients are assigned by chance to take one of two doses of alpha interferon. No one takes placebo. Alpha interferon is injected under the skin. Patients learn to inject themselves, so they may take the medicine at home. Patients are in the study for an indefinite length of time, depending on response to treatment.

**Required:**

- AIDS
- Kaposi's sarcoma of the skin, lymph nodes or hard palate
- at least 12 years old

**Not allowed:**

- any opportunistic infection, now or in the past
- Kaposi's sarcoma of the internal organs
- severe swelling caused by Kaposi's sarcoma
- treatment with alpha interferon in the past
- unable to take ddI because of side effects
- cancer chemotherapy, radiation therapy, or drugs intended to increase or decrease the function of the immune system within 30 days before starting the study

**Location:**

Kaiser San Francisco
Gretchen Van Raalte, RN
(415) 202-3482
(Kaiser health plan members only)

## 38. Kaposi's Sarcoma Treatment: DaunoXome, Adriamycin, Bleomycin, Vincristine

**Title:**

A Randomized Phase III Clinical Trial of DaunoXome Versus Combination Chemotherapy with Adriamycin, Bleomycin and Vincristine (ABV) in the Treatment of HIV-Associated Kaposi's Sarcoma

**Purpose:**

To compare the safety and effectiveness of treatment with the anti-cancer drug DaunoXome to treatment with a combination of the anti-cancer drugs Adriamycin (doxorubicin), bleomycin and vincristine for Kaposi's sarcoma.

**About the study:**

Patients with Kaposi's sarcoma are assigned by chance to be treated with DaunoXome or a combination of the three other drugs. Everyone knows which treatment is being given. Treatments are given every two weeks, by infusion into a vein. The study lasts at least 28 days.

**Required:**

- HIV positive
- advanced Kaposi's sarcoma, which means: at least 25 lesions of the skin or mucous membranes, (or) development of at least 10 lesions in one month, (or) lesions which have joined together or which cause symptoms such as pain (or) involvement of internal organs which causes symptoms, (or) swelling due to blockage of the lymphatic system
- at least 18 years old

**Not allowed:**

- active opportunistic infection
- other chemotherapy in the past (vinblastine injected into lesions is allowed)
- any cancer other than Kaposi's sarcoma
- peripheral neuropathy

**Location:**

Davies HIV Institute
Stephanie LaCarruba, RN
(415) 565-6524

Saint Francis HIVCare
Drew Catapano
(415) 353-6215

Most clinical trials are designed for adults, and do not allow young children to join. Page 65 explains why this is true. But there are a few trials especially for children. See pages 50 through 53 for descriptions of trials for children.

## 39. Non-Hodgkin's Lymphoma Treatment: m-BACOD

**Title:**

A Phase III Randomized Trial of Low-Dose vs. Standard Dose m-BACOD Chemotherapy with rGM-CSF for Treatment of AIDS-Associated Non-Hodgkin's Lymphoma (ACTG 142).

**Purpose:**

To compare the effectiveness of taking a lower dose of the drug combination m-BACOD to taking the standard dose of the drugs together with another drug, GM-CSF.

**About the study:**

Patients are assigned by chance to receive one of the drug doses. Patients know which dose they are taking. Most of the drugs must be given at a clinic visit, but patients taking GM-CSF give those injections at home. Length of the study depends on how well the drug is working, but will be at least several months for most people.

**Required:**

- biopsy or cytology proven non-Hodgkin's lymphoma
- HIV positive

**Not allowed:**

- may not take any other experimental medication or AZT during the study
- may not have an active opportunistic infection (other than MAI) requiring antibiotics
- persistent diarrhea for more than two weeks
- another prior or current cancer (except Kaposi's sarcoma)
- rapidly progressive KS, peripheral edema, or known visceral KS
- primary central nervous system lymphoma
- prior systemic chemotherapy

**Location:**

Kaiser San Francisco
Isabel Gaitan, RN
(415) 202-3486
(Kaiser health plan members only)

SFGH - AIDS Research Group
Lawrence Kaplan, MD
(415) 476-4082, Ext. 84190
Julie Russell, RN
(415) 476-9296, Ext. 84100

## 40. Non-Hodgkin's Lymphoma Treatment: Etoposide, Ifosfamide, Mesna, G-CSF

**Title:**

Phase II Study of Chemotherapy for Relapsed / Refractory AIDS-Associated Non-Hodgkin's Lymphoma Using Etoposide and Continuous Infusion Ifosfamide + Mesna with G-CSF

**Purpose:**

To learn if the drugs Etoposide, Ifosfamide and Mesna will work against Non-Hodgkin's Lymphoma (NHL) in patients with AIDS who have not gotten better with other treatment. (Some patients who have never had other treatment may be eligible, too.)

**About the study:**

All patients receive the same drugs, which are given by infusion into the vein. Patients are hospitalized and treated for as long as the drug is working, or until the disease disappears.

**Required:**

- intermediate or high-grade Non-Hodgkin's lymphoma (NHL)
- measurable tumor
- other treatment has not worked, or only worked temporarily
- at least 18 years old
- no opportunistic infection requiring acute treatment
- some patients who meet all other study requirements, but have never been treated for NHL

**Not allowed:**

- active CMV requiring treatment
- primary central nervous system lymphoma
- other experimental treatment

**Location:**

SFGH - AIDS Research Group
Lawrence D. Kaplan, MD
(415) 476-4082, Ext. 84190

## 41. Hodgkin's Lymphoma Treatment: Bleomycin, Vincristine, Streptozocin, Etoposide

**Title:**

Phase II Study of Combination Chemotherapy of Bleomycin, Vincristine, Streptozocin and Etoposide for AIDS Associated Hodgkin's Lymphoma

**Purpose:**

To see if the combination of the drugs bleomycin, vincristine, streptozocin, and etoposide is an effective treatment for Hodgkin's disease in people with AIDS.

**About the study:**

All patients receive the same drugs, which are given by infusion into the vein. Patients must spend the first three days of screening in the hospital. Treatment lasts at least a few months, depending on how well it is working.

**Required:**

- AIDS diagnosis
- biopsy-proven Hodgkin's lymphoma

**Not allowed:**

- being treated now for an active opportunistic infection

**Location:**

SFGH - AIDS Research Group
Julie Russell, RN
(415) 476-9296, Ext. 84100

## 42. MAC Treatment: Azithromycin, GM-CSF

**Title:**

Project Entitled "Immunotherapy of *Mycobacterium avium* Complex Bacteremia in AIDS Patients with Recombinant Human GM-CSF"

**Purpose:**

To compare the safety and effectiveness of two different treatments for MAC. One treatment uses azithromycin by itself. The other treatment combines azithromycin with GM-CSF (Granulocyte-Macrophage Colony Stimulating Factor).

**About the study:**

Patients are assigned by chance one of two groups. One group takes azithromycin pills once per day for six weeks. The other group takes azithromycin pills and GM-CSF injections once per day for six weeks. GM-CSF is injected under the skin. Patients learn to give their own GM-CSF injections, so they may take all medications at home.The study lasts six weeks.

**Required:**

- AIDS
- positive blood test for MAC
- must take AZT, ddC or ddI
- must take a drug to prevent PCP
- at least 18 years old

**Not allowed:**

- may not take any other drug which acts against MAC for more than seven days within one month before starting the study
- any treatment for MAC within seven days before starting the study
- cancer which must be treated with chemotherapy

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

**If there are words or phrases in this book that you don't understand, you may be able to find explanations in the Glossary, starting on page 81.**

## 43. MAC Treatment: TLC G-65

**Title:**

Multi-Center, Open-Label Study of TLC G-65 Single Agent Loading Dose with Subsequent Combination Therapy in the Treatment of Disseminated MAI in AIDS Patients

**Purpose:**

To find out if it is safe to take TLC G-65 for treatment of MAC infection. To find out if TLC G-65 is an effective treatment for MAC infection.

**About the study:**

This study has two parts: a screening program and a treatment phase. The screening program consists of monthly blood cultures for MAC. Patients who have a positive blood culture for MAC are eligible to enter the treatment phase.

In the treatment phase, patients take TLC G-65 by infusion into a vein. TLC G-65 is given five times per week for one or two weeks, then twice weekly for two or three weeks. For the final eight weeks of treatment, TLC G-65 infusions are given in combination with clarithromycin pills and ethambutol pills. The study lasts 12 weeks.

**Required (for screening program):**

- CD4 cell (T-cell) count below 100
- AIDS, or clinical suspicion of MAC infection

Anyone who meets these requirements may call to enter the screening program.

**Required (for treatment phase):**

- positive blood culture for MAC within eight weeks before starting the study
- no other treatment for MAC within seven days before starting the study

**Not allowed:**

- allergy to eggs
- kidney disease
- active opportunistic infection other than MAC
- loss of more than 30% of body weight within the past six months
- patients who develop MAC while taking clarithromycin to prevent MAC

**Location:**

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 44. MAC Treatment: Azithromycin

**Title:**

An Open Label Study of the Use of Azithromycin in Patients with Symptomatic Disseminated *Mycobacterium avium-Intracellulare* Complex (MAC) Infection Failing Current Therapy

**Purpose:**

To make the drug azithromycin available to people with disseminated *Mycobacterium avium-Intracellulare* Complex (MAC) who cannot take or have not improved with other treatment. The study will also collect information on how well the drug works.

**About the study:**

All patients are given azithromycin either in pill form or as an IV infusion. Patients must make monthly clinic visits for tests, and to receive drug supply. Patients may take the drug for as long as it is working.

**Required:**

- documented disseminated MAC (blood, bone marrow, or liver biopsy culture)
- one or more of the following symptoms: fever, night sweats, anorexia, weight loss, fatigue or malaise
- at least 2 months of treatment for MAC, or less than 2 months treatment with severe side effects
- approval of drug company (Pfizer)

**Not allowed:**

- may not take other experimental drugs within 7 days before starting the study. Drugs available under a treatment IND are allowed.

**Location:**

Any healthcare provider can enroll eligible patients into this program by calling Pfizer at 1-800-742-3029. Ask your provider for details.

## 45. MAC Treatment: Clarithromycin, Clofazimine, Ethambutol

**Title:**

An Open-Label, Multicenter Study of the Safety and Efficacy of Clarithromycin Plus Clofazimine With or Without Ethambutol in the Treatment of Disseminated *Mycobacterium avium* Complex (MAC) Infection in HIV-Infected Patients with CD4 Counts $\leq$ 100 Cells / mm$^3$ (Abbott Protocol M92-806)

**Purpose:**

To compare the effectiveness of two combinations of drugs for treatment of MAC. To learn if the drugs are safe to use in these combinations.

**About the study:**

All patients in this study take clarithromycin and clofazimine pills every day. In addition, if their doctor thinks it is a good idea, some patients also take ethambutol pills. Everyone knows which drugs are being taken, and at what dose. Patients may be on study for varying lengths of time, depending on response to treatment or progression of disease. Patients who respond well to treatment may be allowed to take the drugs after the end of the study to prevent MAC disease from coming back.

**Required:**

- HIV positive
- must have been enrolled in Protocol M91-561 or Protocol M91-561X, a previous clarithromycin study sponsored by Abbott Laboratories
- clinical symptoms of MAC infection or positive blood test for MAC
- at least 12 years old

**Not allowed:**

- taking any other drugs which act against MAC infection (except drugs taken as part of Protocol M91-561 or M91-561X)
- cancer which must be treated with chemotherapy
- any active opportunistic infection other than MAC. Opportunistic infections which are now on "maintenance" treatment may be allowed.
- taking other experimental drugs (D4T and EPO are allowed)

**Location:**

Kaiser San Francisco
Isabel Gaitan, RN
(415) 202-3486
(Kaiser health plan members only)

## 46. MAC Treatment: Clarithromycin, Rifabutin, Ethambutol

**Title:**

A Three-Arm Comparative Trial for the Treatment of MAC Bacteremia in AIDS: A Clarithromycin / Ethambutol Regimen Containing Rifabutin (900 mg.) or Rifabutin (600 mg.) or Placebo
(Adria Protocol CS 087250-999)

**Purpose:**

To find out if rifabutin is helpful for treatment of MAC infection, when used in combination with clarithromycin and ethambutol.

**About the study:**

Everyone in this study takes a combination of the drugs clarithromycin and ethambutol. In addition, patients are assigned by chance to also take one of two doses of rifabutin or a placebo. Neither the patients nor their doctors know which are taking rifabutin until the study ends. There is no scheduled end date for the study; patients should expect to take their assigned medicines indefinitely, as long as the drugs are helping and patients are not having severe side effects.

**Required:**

- HIV positive
- one positive blood test for MAC *and* at least two clinical symptoms of MAC, *or* two positive blood tests for MAC without symptoms of disease
- at least 13 years old

**Not allowed:**

- taking any other drugs which act against MAC within 14 days before starting the study

**Location:**

ViRx, Inc.
Michael Baker, PhD
(415) 474-2233

## 47. MAC Prevention: Clarithromycin, Rifabutin

**Title:**

A Prospective, Randomized, Comparative Study of the Safety and Efficacy of Clarithromycin versus Rifabutin versus the Combination of Clarithromycin Plus Rifabutin for the Prevention of *Mycobacterium avium* Complex (MAC) Bacteremia or Disseminated MAC Disease in HIV-Infected Patients with CD4 Lymphocyte Counts ≤ 100 Cells / mm$^3$
(ACTG 196 / CPCRA 009)

**Purpose:**

To compare the effectiveness of taking clarithromycin by itself, rifabutin by itself or the combination of clarithromycin and rifabutin for prevention of MAC disease. To learn more about the safety of taking these drugs to prevent MAC disease.

**About the study:**

Patients are assigned by chance to take clarithromycin, rifabutin or the combination of both drugs. Neither the patients nor their doctors know which drugs are being taken until the study ends. All drugs are taken by mouth. Patients may be in this study for up to two years.

**Required:**

- HIV positive
- less than 100 CD4 cells (T-cells)
- negative blood test for MAC
- at least 12 years old

**Not allowed:**

- people who have MAC now
- people who have TB or are taking drugs to prevent TB
- taking other drugs which act against MAC for more than four months before starting the study
- severe diarrhea which has lasted more than six weeks

**Location:**

Community Consortium. Ask your health care provider (see page 75).

Highland General Hospital
Adult Immunology Clinic
Terry Cooper
(510) 437-4512

SFGH - AIDS Research Group
Rowena Mah, RN
(415) 476-9296, Ext. 84093

## 48. MAC Prevention: Clarithromycin

**Title:**

A Prospective, Randomized, Double-blind, Multicenter, Placebo-Controlled Study of the safety and Efficacy of Clarithromycin for the Prevention of Disseminated *Mycobacterium avium* Complex (MAC) Infection in HIV-Infected Patients with CD4 Counts Less Than or Equal to 100 Cells / mm$^3$

**Purpose:**

To find out if taking clarithromycin can help prevent people with HIV from getting MAC. To find out if it is safe to take clarithromycin for a long period of time.

**About the study:**

Patients are assigned by chance to take clarithromycin or a placebo twice per day for two years. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts two years.

**Required:**

- HIV positive, ARC or AIDS
- less than 100 CD4 cells (T-cells)
- negative blood culture for MAC
- at least 12 years old

**Not allowed:**

- known or suspected MAC
- taking any other drug which acts against MAC

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

Kaiser San Francisco
Isabel Gaitan, RN
(415) 202-3486
(Kaiser health plan members only)

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

You may not be sure just what a clinical trial is. Or, even if you want to join a trial, you may not know how. See pages 57 through 61 for answers to a few of the most commonly asked questions about what a clinical trial is, and how you can join a trial.

## 49. MAC Prevention: Rifabutin

**Title:**

Rifabutin Therapy for the Prevention of *Mycobacterium avium* Complex (MAC) Bacteremia in HIV Positive Patients with CD4 Counts Less Than or Equal to 200: Treatment IND Study

**Purpose:**

To make rifabutin available to HIV positive patients with less than 200 CD4 cells (T-cells). To find out if rifabutin is effective for prevention of MAC in these patients.

**About the study:**

This is an expanded access program for rifabutin. All patients take the same dose of rifabutin once per day.

**Required:**

- HIV positive, ARC or AIDS
- less than 200 CD4 cells (T-cells)
- negative blood culture for MAC, taken within 21 days of starting the study
- at least 12 years old

**Not allowed:**

- anyone who has MAC now, or had MAC in the past
- taking other experimental drugs. For purposes of this program, drugs available under another expanded access program are not considered experimental.

**Location:**

Any health care provider can enroll eligible patients into this program by calling the PACT Rifabutin Treatment IND Study Center at 1-800-552-7228. Ask your health care provider for details.

## 50. MAC and Fungal Prevention: Azithromycin, Rifabutin, Fluconazole

**Title:**

A Randomized Study of Daily and Intermittent Prophylactic Regimens for the Prevention of Disseminated *Mycobacterium avium* Complex (MAC) and Fungal Infections in HIV Infected Patients (Protocol 066-174)

**Purpose:**

To find out if taking azithromycin, rifabutin or both drugs together can help prevent people with HIV from getting MAC disease. To find out if taking fluconazole can help prevent people with HIV from getting certain fungal infections. To learn more about the safety of taking these combinations of drugs.

**About the study:**

Patients are assigned by chance to take azithromycin by itself, rifabutin by itself or a combination of both drugs. In addition, patients are assigned by chance to also take fluconazole, either every day or once per week. All drugs are taken by mouth. Neither the patients nor their doctors know which combination of drugs is being taken until the study ends. The study lasts at least one year.

**Required:**

- HIV positive
- less than 100 CD4 cells (T-cells)
- at least 12 years old

**Not allowed:**

- patients who now have certain diseases, including: MAC, TB or an active fungal infection
- being treated now for an active opportunistic infection

**Location:**

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

Santa Clara County Early Intervention Program
Brenda Cayme, RN
(415) 364-6563

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 51. PCP Treatment: Atovaquone

**Title:**

A Phase II Randomized, Open Label Study to Evaluate the Safety and Efficacy of Atovaquone Suspension in AIDS Patients with Mild to Moderate PCP (BW 202)

**Purpose:**

To find out if a liquid form of atovaquone is a safe and effective treatment for PCP.

**About the study:**

Patients are assigned by chance to one of four treatment groups. Three of the groups take atovaquone liquid either once or twice per day for 21 days. The fourth group takes atovaquone liquid twice per day, plus Septra® pills three times per day for 21 days. Patients know which drug(s) they are taking.

**Required:**

- AIDS
- mild to moderate PCP that has not been treated with other drugs
- at least 13 years old

**Not allowed:**

- severe PCP, where there is danger of respiratory failure
- being treated for PCP within four weeks before starting this study
- taking other drugs which might act against PCP
- taking other experimental drugs
- severe digestive problems or vomiting
- other lung diseases

**Location:**

Davies Medical Center
Stephanie LaCarruba, RN
(415) 565-6524

## 52. PCP Treatment: Trimetrexate

**Title:**

Trimetrexate Treatment IND for *Pneumocystis carinii* Pneumonia (PCP)

**Purpose:**

To make the drug trimetrexate available to people with PCP who cannot tolerate, or don't get better with, trimethoprim / sulfamethoxazole (also called Septra® or Bactrim™ ) or pentamidine.

**About the study:**

Patients must stay in the hospital for 21 days while being treated trimetrexate and leucovorin, and then for three days with leucovorin alone. The drugs are given by infusion into a vein.

**Required:**

- AIDS
- PCP confirmed by bronchoscopy within the last 15 days
- cannot take Septra® (Bactrim™ ) or pentamidine *or* do not get better with these drugs

**Location:**

Any health care provider can enroll eligible patients by calling the National Institute of Allergy and Infectious Diseases (NIAID) at1-800-537-9978. Ask your provider for details.

## 53. PCP Prevention: Trimethoprim / Sulfamethoxazole (TMS)

**Title:**

A Randomized, Comparative, Prospective Study of Daily Trimethoprim / Sulfamethoxazole (TMS) and Thrice Weekly TMS for Prophylaxis Against PCP in HIV-Infected Patients (CPCRA 006)

**Purpose:**

To compare the safety and effectiveness of two different doses of trimethoprim / sulfamethoxazole (TMS, also called Septra® or Bactrim™) to prevent people with HIV from getting *Pneumocystis carinii* Pneumonia (PCP).

**About the study:**

Patients are assigned by chance to take one TMS tablet daily or one TMS tablet three times per week. Both the patient and the physician know which dosing schedule is being followed. The study lasts up to 2 1/2 years.

**Required:**

- HIV positive
- CD4 cell (T-cell) count of 200 or below, or had PCP in the past
- at least 13 years old

**Not allowed:**

- taking any other drug which acts against PCP
- active PCP. If a patient has active PCP, it must be treated before s/he can start the study.

**Location:**

Community Consortium. Ask your health care provider (see page 75).

Kaiser San Francisco
Allen Harris, RN,C
(415) 202-3481
(Kaiser health plan members only)

## 54. PCP Prevention: Pentamidine, Dapsone

**Title:**

A Randomized, Comparative, Prospective Study of Monthly Aerosolized Pentamidine and Thrice Weekly Dapsone for Prophylaxis Against PCP in HIV-Infected Patients Who Are Intolerant to Trimethoprim and / or Sulfonamides (CPCRA 013)

**Purpose:**

To compare the safety and effectiveness of aerosolized pentamidine (AP) and dapsone to prevent people with HIV from getting *Pneumocystis carinii* Pneumonia (PCP). This study is for people who cannot take trimethoprim / sulfamethoxazole (also called Septra® or Bactrim™), a drug often used to prevent PCP.

**About the study:**

Patients are assigned by chance to take dapsone (100 mg.) three times per week or aerosolized pentamidine (300 mg.) once per month. Dapsone is a tablet. Aerosolized pentamidine is inhaled into the lungs as a very fine mist, using a device called a nebulizer. Both the patient and the physician know which drug is being taken. The study lasts up to 2 1/2 years.

**Required:**

- HIV positive
- CD4 cell (T-cell) count of 200 or below, or had PCP in the past
- cannot take Septra® or Bactrim™ because of side effects
- at least 13 years old

**Not allowed:**

- taking any other drug which acts against PCP
- active PCP. If a patient has active PCP, it must be treated before s/he can start the study.

**Location:**

Community Consortium. Ask your health care provider (see page 75).

Kaiser San Francisco
Allen Harris, RN,C
(415) 202-3481
(Kaiser health plan members only)

There are many organizations that can help you learn more about HIV disease and about treatments for HIV disease. You may want to read the Resources section starting on page 77 for more information on these groups.

## 55. Peripheral Neuropathy Treatment: Acupuncture, Amitriptyline

**Title:**

The Efficacy of a Standardized Acupuncture Regimen and Amitriptyline Compared with Placebo as a Treatment For Pain Caused by Peripheral Neuropathy in HIV-Infected Patients (CPCRA 022)

**Purpose:**

To compare the effectiveness of three treatments for painful peripheral neuropathy. The treatments that are being studied are: 1) acupuncture, 2) amitriptyline and 3) the combination of acupuncture and amitriptyline.

**About the study:**

Patients are assigned by chance to one of four study groups. The first group is treated with acupuncture and amitriptyline. The second group is treated with acupuncture and a placebo. The third group is treated with amitriptyline and sham acupuncture (also called "alternate points" acupuncture). Sham acupuncture involves placing the acupuncture needles in points that are not harmful, but have not been proven to be helpful. The fourth group is treated with a placebo and sham acupuncture. Patients do not know which treatment is being given until the study ends. Patients must keep a daily pain diary while in the study. The study lasts 18 weeks.

**Required:**

- painful peripheral neuropathy caused by HIV
- at least 13 years old

**Not allowed:**

- active opportunistic infection
- taking anti-depressant drugs. Patients who have been taking anti-depressant drugs may join the study if they stop taking them before starting the study.

**Location:**

Community Consortium. Ask your health care provider (see page 75).

## 56. Peripheral Neuropathy Treatment: Mexiletine

**Title:**

A Randomized Double-Blind Crossover Study of the Safety and Efficacy of Mexiletine versus Placebo in the Treatment of HIV Infected Patients with Painful Peripheral Neuropathy

**Purpose:**

To learn if the drug Mexiletine is a good way to treat painful peripheral neuropathy in people with HIV disease.

**About the study:**

Patients are assigned by chance to take either Mexiletine tablets or placebo. Neither the patients nor their doctors know which the patient is taking until the study ends. Pills are taken three times per day for thirteen weeks, with one week off in the middle. Patients visit the clinic for tests every two weeks; an electrocardiogram is performed at four of the visits.

**Required:**

- at least 18 years old
- HIV-related peripheral neuropathy requiring treatment

**Not allowed:**

- prior or current treatment with ddC, ddI or vincristine
- current or past peptic ulcer
- active herpes or CMV infection
- history of seizures or use of anticonvulsant drugs
- extensive Kaposi's sarcoma requiring systemic chemotherapy
- current cancers other than KS
- certain active opportunistic infections

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 57. Syphilis Treatment: Ceftriaxone

**Title:**

A Prospective Evaluation of Ceftriaxone in the Treatment of Asymptomatic and Symptomatic Neurosyphilis in Patients with HIV Infection and AIDS

**Purpose:**

To learn if ceftriaxone is effective for the treatment of syphilis involving the central nervous system.

**About the study:**

All patients receive the same dose of ceftriaxone, injected into a muscle once per day for ten days. Lumbar punctures are performed at the start of the study and four times during a two-year follow-up period.

**Required:**

- 18 years of age or older
- HIV positive
- Evidence of latent syphilis, as determined by a blood test
- White blood cells or protein in cerebro-spinal fluid obtained from lumbar puncture

**Not allowed:**

- Evidence of other central nervous system disease

**Location:**

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 58. Syphilis Treatment: Penicillin

**Title:**

A Randomized Comparative Trial of Standard Low Dose Versus High Dose Penicillin Regimens in the Treatment of Latent Syphilis in Patients with HIV Infection and AIDS

**Purpose:**

To compare the effectiveness of two dosage levels of penicillin for the treatment of latent syphilis which does not involve the central nervous system.

**About the study:**

Patients are assigned by chance to receive one of two dosage levels of penicillin. The low dose is injected into a muscle once per week for three weeks. The high dose is injected into a muscle once per day for ten days. Lumbar punctures are performed at the start of the study and four times during a two-year follow-up period.

**Required:**

- 18 years of age or older
- HIV positive
- Evidence of latent syphilis, as determined by a blood test

**Not allowed:**

- Abnormal cerebro-spinal fluid obtained from lumbar puncture
- Evidence of other central nervous system disease

**Location:**

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 59. Syphilis Treatment: Penicillin

**Title:**

A Diagnostic and Therapeutic Evaluation of High Dose Penicillin Therapy in the Treatment of Possible Neurosyphilis in Patients with HIV Infection and AIDS

**Purpose:**

To learn if high dose penicillin is effective for treatment of syphilis involving the central nervous system.

**About the study:**

All patients receive the same dose of penicillin, injected into a muscle once per day for ten days. Lumbar punctures are performed at the start of the study and four times during a two-year follow-up period.

**Required:**

- 18 years of age or older
- HIV positive
- Evidence of latent syphilis, as determined by a blood test
- White blood cells or protein in cerebro-spinal fluid obtained from lumbar puncture

**Not allowed:**

- Evidence of other central nervous system disease

**Location:**

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 60. Toxoplasmosis Treatment: Azithromycin

**Title:**

Study of Azithromycin in the Treatment of Toxoplasmic Encephalitis in AIDS Patients who Cannot be Treated with Conventional Therapy

**Purpose:**

To make the drug azithromycin available to people with toxoplasmic encephalitis ("toxo") who cannot take the drugs usually used to treat it (sulfa drugs or pyrimethamine), or who have not gotten better after being treated with these drugs. To learn if this drug is a safe and effective treatment for toxo.

**About the study:**

All patients take the same dose of azithromycin for 28 days. If the drug works well, patients may be allowed to take it indefinitely to see if it will help prevent them from getting toxo again.

**Required:**

- AIDS
- toxoplasmic encephalitis ("toxo")
- unable to take other drugs for treatment of toxo due to side effects, ***or***
- did not get better with other treatment for toxo

**Location:**

Any health care provider can enroll eligible patients into this study by calling Pfizer at 1-800-742-3029. Ask your provider for details.

## 61. Toxoplasmosis Prevention: Pyrimethamine

**Title:**

A Study of Prophylactic Pyrimethamine Therapy for Prevention of Toxoplasmosis Infection in Individuals with Advanced HIV Infection

**Purpose:**

To learn if taking the drug pyrimethamine can help prevent people with HIV from getting toxoplasmosis.

**About the trial:**

Patients are assigned by chance to take pyrimethamine pills once per week or three times per week. No one takes placebo. The trial lasts two years.

**Required:**

- shown by a blood test to have been exposed to *Toxoplasma gondii*
- HIV positive
- CD4 cell (T-cell) counts below 200

**Not allowed:**

- prior diagnosis of toxoplasmosis
- other known CNS disease

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 62. *M. tuberculosis* Treatment: INH, Rifampin, PZA, Ethambutol, Levofloxacin,

**Title:**

The Treatment of Pulmonary *Mycobacterium tuberculosis* in HIV Infection (ACTG 222)

**Purpose:**

A combination of the drugs isoniazid (INH), rifampin, pyrazinamide (PZA) and ethambutol is often used as a treatment for tuberculosis (TB). But some kinds of TB are resistant to this combination of drugs. TB which is resistant to treatment with the standard combination of drugs is called multidrug-resistant TB. This study will compare the effectiveness of this standard combination of drugs plus levofloxacin to that of the same combination of drugs without levofloxacin for treatment of TB in people with HIV infection. Researchers hope to learn about the effectiveness of these drugs for treating multidrug-resistant TB as well as TB which is not resistant.

**About the study:**

Everyone in this study takes the standard four-drug combination treatment for TB. Some patients are assigned by chance to also take levofloxacin. Everyone knows which combination of drugs is being taken. The study lasts at least two years, and for some patients may last as long as four years.

**Required:**

- HIV positive
- TB in the lungs
- at least 13 years old. Patients who come from an area with a high rate of multidrug-resistant TB must be at least 18 years old.

**Not allowed:**

- patients who are known to have multidrug-resistant TB
- more than two weeks of treatment for TB before starting the study

**Location:**

Kaiser San Francisco
Gretchen Van Raalte, RN
(415) 202-3482
(Kaiser health plan members only)

If you are between the ages of 13 and 18 you may not be sure where you "fit in" with clinical trials. You may be eligible for trials designed for either children or adults. If you are interested in joining a trial, special health care and support programs for youth can help you sort through the confusion. Pages 67 and 68 will help you get started.

## 63. *M. tuberculosis* Treatment: INH, Rifampin, PZA, Ethambutol

**Title:**

Treatment of Tuberculosis in Patients with Human Immunodeficiency Virus Infection: Effects of a Standard Six-Month Regimen

**Purpose:**

To learn if the drugs isoniazid (INH), Rifampin, Pyrazinamide (PZA) and Ethambutol are effective treatments for people with HIV infection who have tuberculosis.

**About the study:**

All patients take the drugs INH, rifampin, and PZA for 6 months (in pill form). Patients who might be resistant to these drugs also receive ethambutol. Patients are seen in the clinic monthly. *Note:* This study will close in September.

**Required:**

- HIV positive
- tested positive for tuberculosis

**Not allowed:**

- born in Asia

**Location:**

SFGH - Tuberculosis Clinic
Gisela Schecter, MD
(415) 206-8524

## 64. *M. tuberculosis* Prevention: INH

**Title:**

Prophylaxis Against Tuberculosis (TB) in Patients with Human Immunodeficiency Virus (HIV) Infection and Suspected Latent Tuberculosis Infection (CPCRA 005)

**Purpose:**

To find out if taking the drug isoniazid (also called INH) for six months can help prevent tuberculosis in people with HIV infection who are at high risk for tuberculosis but have a negative skin test.

**About the study:**

Patients are assigned by chance to take INH pills or placebo once daily for six months. Neither the patients nor their doctors know which is being taken until the study ends. In addition, everyone on the study also takes vitamin $B_6$ pills once daily for six months. Vitamin $B_6$ is taken to help prevent side effects people sometimes get from taking INH. After six months of treatment, people are followed every three months until the end of the study to see if tuberculosis develops. Total length of time on the study is two to four years, with an average of three years.

**Required:**

- HIV positive
- in a high risk group for tuberculosis. High risk groups include people from Asia, Latin America or Africa; people who are homeless or living in a shelter or nursing home; and people who use alcohol or street drugs.
- negative PPD (skin test for tuberculosis)
- at least 13 years old

**Not allowed:**

- current active tuberculosis
- positive PPD (skin test for tuberculosis)
- taking other drugs used to treat TB
- hepatitis
- severe peripheral neuropathy

**Location:**

Community Consortium. Ask your health care provider (see page 75).

Kaiser San Francisco
Allen Harris, RN,C
(415) 202-3481
(Kaiser health plan members only)

## 65. *M. tuberculosis* Prevention: Rifampin, PZA, INH

**Title:**

Prophylaxis Against *Mycobacterium tuberculosis* (MTb) in Patients who are Infected with the Human Immunodeficiency Virus (HIV) and Suspected or Confirmed Latent MTb Infection (ACTG 177)

**Purpose:**

To learn if taking the drugs rifampin and pyrazinamide (PZA) together, or isoniazid (INH) by itself, can help prevent people with both HIV infection and TB infection from getting tuberculosis.

**About the study:**

Patients with a positive skin test for TB, but without symptoms of TB, are assigned by chance to one of two study groups. One group takes rifampin and pyrazinamide pills every day for 60 days. The second group takes INH pills and vitamin $B_6$ every day for one year. Everyone knows which drug(s) they are taking. Patients are studied for up to three years to see if TB develops.

**Required:**

- HIV positive
- positive PPD (skin test for tuberculosis)
- at least 13 years old

**Not allowed:**

- current active tuberculosis
- use of other drugs which might prevent or cure tuberculosis
- active hepatitis or peripheral neuropathy

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

Highland General Hospital
Adult Immunology Clinic
Terry Cooper
(510) 437-4512

Kaiser San Francisco
Gretchen Van Raalte, RN
(415) 202-3482
(Kaiser health plan members only)

SFGH - AIDS Research Group
Linda Johnson, RN
(415) 476-9296, Ext. 84099

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

Stanford University Medical Center
ACTG Office
(415) 723-6231

## 66. Weight Loss: TPN with Alanyl-Glutamine Dipeptide

**Title:**

An Evaluation of the Safety and Efficacy of Standard and Glutamine-Enriched Total Parenteral Nutrition (TPN) in Patients with HIV Disease: A Prospective, Controlled, Randomized, Double-Blind Study

**Purpose:**

People with HIV sometimes have severe unintended weight loss, and cannot take in enough nutrition by mouth to regain and maintain their weight. Total parenteral nutrition (TPN) is a method of giving these people a liquid nutritional supplement which contains a mixture of highly concentrated nutrients. The purpose of the study is to find out if TPN containing a special amino acid is more effective than standard TPN in helping people gain and maintain weight. Researchers are also studying the effects of TPN on the digestive system, overall disease progression, immune function, quality of life, the kinds of problems (if any) that may arise, and total cost of medical care in patients with HIV disease.

**About the study:**

All patients in this study receive TPN. Some receive standard TPN, and some are assigned by chance to receive TPN with an added ingredient, an amino acid called l-alanyl l-glutamine. TPN is given through a catheter (a tube, sometimes called a "central line") placed in the chest, just below the collarbone. Patients must go to the hospital for a minor surgical procedure to place the catheter in the chest. Then they may receive TPN at home. The study lasts three months.

**Required:**

- HIV positive, ARC or AIDS
- unintentional loss of at least five percent of usual weight
- unable to eat enough to maintain weight or to regain lost weight in one month
- severe nausea and vomiting that is not helped by taking medicine
- severe diarrhea that is not helped by taking medicine

**Not allowed:**

- anyone who is unable to have TPN at home for any reason

**Location:**

Jeffrey M. Aron, MD
(415) 563-3534

Lifesource, Inc.
Jeanine Loughner, RD
(415) 749-6440

## 67. Weight Loss: Human Growth Hormone

**Title:**

A Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Multi-Center Study of Recombinant Human Growth Hormone in the Treatment of HIV-Associated Catabolism / Wasting

**Purpose:**

To find out if taking recombinant human growth hormone (rhGH) can help slow or prevent weight loss caused by HIV disease.

**About the study:**

Patients are assigned by chance to take rhGH or placebo, given by injection under the skin. Neither the patients nor their doctors know which is being taken until the study ends. Patients learn to inject themselves, so they may take the treatments at home. The study lasts 12 weeks. After the study ends, if there are no serious side effects, patients may take open label rhGH injections for as long as the drug is helping.

**Required:**

- HIV positive, ARC or AIDS
- intended weight loss of at least five percent
- at least 18 years old

**Not allowed:**

- serious untreated infection
- fever above 101 F during the two weeks before starting the study
- active cancer (localized KS is allowed)
- severe diarrhea or digestive problems
- any of several medical conditions or diseases, including: diabetes, unstable high blood pressure, heart disease, dementia
- taking any of several other drugs, including: steroids, appetite stimulants, interferon or other experimental drugs

**Location:**

SFGH - Koret Center
Viva Tai, RD, MPH
(415) 206-4090

If there are words or phrases in this book that you don't understand, you may be able to find explanations in the Glossary, starting on page 81.

## 68. Weight Loss: MJ-7068

**Title:**

Acceptance, Tolerance, and Effectiveness of MJ-7068, A Complete Ready-To-Use Nutritional Product For AIDS and ARC Outpatients Suffering From Fat Malabsorption.

**Purpose:**

To learn if the new nutritional drink, MJ-7068, can improve nutrition for people with AIDS and ARC who have diarrhea because they cannot absorb the fats found in many foods.

**About the study:**

This is a two part study. Part one is a 16 day treatment period during which patients are assigned by chance to consume 90% of their estimated caloric needs from a nutritional drink containing one of two types of fat. In part two, patients are given the special fat formula to drink for up to one year. Nutritional status is closely monitored throughout the study.

**Required:**

- AIDS or ARC
- at least 80% of ideal body weight
- uncontrolled diarrhea caused by inability to absorb fats
- if taking AZT, ddC, marinol, Megace or ddI, must have been on the drug for at least 8 weeks
- not hospitalized

**Location:**

SFGH - GI Unit
Kristin Weaver, RN, MS
(415) 206-8822

## 69. Muscle Wasting: Oxandrolone

**Title:**

Oxandrolone: Phase II, Placebo-Controlled Study for HIV-Associated Myopathy / Muscle Weakness

**Purpose:**

To find out if oxandrolone can help slow or prevent loss of muscle caused by HIV disease. To find out if oxandrolone is safe to use for this condition.

**About the study:**

Patients are assigned by chance to take oxandrolone pills or a placebo. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts 16 weeks. If patients taking oxandrolone have been helped by the drug, they may continue to take it after the study ends. If they were in the group taking placebo, they may take open-label oxandrolone after the study ends.

**Required:**

- muscle loss caused by HIV

**Not allowed:**

- taking steroids or any other drugs intended to stimulate appetite or increase muscle size

**Location:**

Marin County Specialty Clinic
Janice Good, RN
(415) 499-6796

## 70. Treatment of AIDS-Related Neurological Problems: Nimodipine

**Title:**

Randomized, Double Blind, Placebo Controlled Trial of Nimodipine for the Neurological Manifestations of HIV-1 as Concurrent Therapy with Zidovudine

**Purpose:**

HIV sometimes causes problems in the brain and nervous system, affecting such things as thought processes, movement, coordination, and behavior. The purpose of this study is to find out if nimodipine may be helpful in treating these kinds of problems. Researchers also want to find out if it is safe for people with HIV infection to take nimodipine along with AZT.

**About the study:**

All patients in this study take AZT. Patients are assigned by chance to also take nimodipine or placebo. Neither the patients nor their doctors know which is being taken until the study ends. Two lumber punctures are required during the course of the study. The study lasts 20 weeks.

**Required:**

- HIV positive, ARC or AIDS
- HIV-Associated Motor / Cognitive Complex (also known as AIDS Dementia Complex), with problems in thinking, movement, coordination or behavior
- taking any approved anti-HIV drug at a stable dose for at least eight weeks

**Not allowed:**

- neurological problems caused by anything other than HIV

**Location:**

UCSF - AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

## 71. Pharmacokinetics: AZT and Mexiletine

**Title:**

Pharmacokinetics of AZT and Mexiletine use concomitantly in HIV infected patients

**Purpose:**

To learn how taking the drugs AZT and Mexiletine, together, affects the way they are absorbed and processed by the body. AZT is a drug that is taken by many people with HIV disease; Mexiletine is a new drug that can be used for peripheral neuropathy.

**About the study:**

Everyone takes AZT and Mexiletine together for one week, then everyone takes Mexiletine alone for ten days. Patients take nothing for three days, and then take AZT alone, as they did before the study began. Blood tests are drawn at the beginning of the study, whenever drug treatment is changed, and at the end of the study. People already taking AZT are required to stop using it for a period of time during the study.

**Required:**

- HIV positive
- at least 18 years old
- must be able to take a daily 500 - 600 mg. dose of AZT for a minimum of two weeks before the study begins

**Not allowed:**

- current or prior peptic ulcer
- active drug or alcohol abuse
- currently using hepatic enzyme inducers (for example, rifampin, phenobarbitol), diuretics, investigational drugs, or drugs that can cause damage to the central nervous system, heart, or gastro-intestinal tract

**Location:**

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 72. Pharmacokinetics: Oral Ganciclovir

**Title:**

A Randomized, Comparative Pharmacokinetic Study of Oral Ganciclovir After Treatment with IV Ganciclovir for Cytomegalovirus Colitis in AIDS Patients (ACTG 183)

**Purpose:**

To learn how oral ganciclovir is absorbed and processed by the body in patients who have been treated with intravenous (IV) ganciclovir for CMV colitis (bowel disease caused by CMV in the colon)

**About the study:**

Patients with CMV colitis are treated for 21 days with ganciclovir, given by infusion into a vein. Then, they are assigned by chance to take one of three doses of ganciclovir by mouth three times per day for five days. Total length of time on the study is 26 days. Blood tests on days 25 and 26 measure the level of ganciclovir in the body.

**Required:**

- HIV positive
- biopsy-proven CMV infection of the colon
- colitis
- more than three liquid bowel movements per day

**Not allowed:**

- CMV retinitis diagnosed within 14 days before starting the study. CMV retinitis which was diagnosed earlier is allowed.
- active opportunistic infection which must be treated with drugs known to lower the white blood cell count or cause damage to the kidneys
- may not take acyclovir pills while on this study
- may not take any experimental drugs or drugs intended to boost the function of the immune system within 14 days before starting the study. Drugs available through a treatment IND are allowed.

**Location:**

SFGH - AIDS Research Group
Ted Bush, RN
(415) 476-9296, Ext. 84098

Most clinical trials are designed for adults, and do not allow young children to join. Page 65 explains why this is true. But there are a few trials especially for children. See pages 50 through 53 for descriptions of trials for children.

## 73. Pharmacokinetics: Itraconazole

**Title:**

An Open, Randomized Study of the Effect of Coadministration of a Cola Beverage on the Bioavailability of a Single 200 mg. Dose of Itraconazole Capsule in AIDS Patients

**Purpose:**

To learn how taking itraconazole with a cola beverage affects the way it is absorbed and processed by the body.

**About the study:**

Patients are assigned by chance to take one itraconazole pill with either cola or water at each of two study visits. If they take the pill with cola the first time, they take it with water the second time. If they take the pill with water the first time, they take it with cola the second time. A very small tube is inserted into the stomach to measure the level of stomach acid continuously for six hours after each pill is taken. Patients must stay in the hospital or clinic while this is being done. Patients must return for blood tests to measure the amount of itraconazole in the blood at 24, 48 and 72 hours after taking the pill. The study lasts about three weeks. Patients are paid $200 after the study is finished.

**Required:**

- AIDS
- less than 100 CD4 cells (T-cells)
- non-smokers only

**Not allowed:**

- taking any experimental drugs within 30 days of starting the study. Drugs available through an expanded access program are not considered experimental for purposes of this study.
- taking certain other drugs, including rifampin, phenobarbital, phenytoin, carbamazepine, terfenadine, omeprazole, astemizole, and histamine blockers
- liver disease
- severe diarrhea

**Location:**

Marcus A. Conant, MD Clinical Research
Steven Ellis, RN
Gordon Sanford, PA-C
(415) 923-0222

## 74. Pharmacokinetics: Rifabutin, Clarithromycin, Azithromycin

**Title:**

Evaluation of the Safety, Tolerance and Pharmacokinetics of Rifabutin / Clarithromycin Combination and Rifabutin / Azithromycin Combination in HIV-Infected Patients (DATRI 001)

**Purpose:**

To learn if it is safe for people to take the drugs rifabutin and clarithromycin together. To learn if it is safe for people to take the drugs rifabutin and azithromycin together. To learn about how these combinations of drugs are absorbed and processed by the body.

**About the study:**

Patients are assigned by chance to one of four study groups. Each study group takes a different combination of the study drugs. Blood tests measure the level of the drugs in the blood stream several times during the course of the study. Patients stay in the hospital overnight three times for tests, on days 14, 15 and 42. The study lasts eight weeks. Patients are paid $325 for being in the study.

**Required:**

- HIV positive
- taking AZT or ddI for at least one month before starting study
- at least 18 years old

**Not allowed:**

- MAC infection or any other active opportunistic infection
- maintenance treatment for CMV, cryptococcal meningitis or toxoplasmosis
- taking other drugs which might interact with the study drugs

**Location:**

Davies HIV Institute
Stephanie LaCarruba, RN
(415) 565-6524

## 75. Pharmacokinetics: Ciprofloxacin and Rifampin

**Title:**

Pharmacokinetics of Combinations of Zidovudine, Ciprofloxacin and Rifampin in Normal Volunteers and Patients with AIDS

**Purpose:**

To learn how taking two commonly used antibiotics, ciprofloxacin and rifampin, in combination, affects the way they are absorbed and processed by the body.

**About the study:**

Everyone in this study takes both ciprofloxacin and rifampin pills every day for eleven days. Participants are paid $100.

**Required:**

- between 20 - 45 years old
- may be either HIV positive or negative

**Location:**

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 76. Sinusitis Treatment: Decongestants, Nasal Steroids, Antibiotics

**Title:**

Management of HIV-Infected Patients at Risk of Recurrent Purulent Sinusitis: Role of Anti-Inflammatory, Antibacterial, and Decongestant Prophylaxis
(ACTG 186)

**Purpose:**

Many people with HIV infection are bothered with sinusitis (sinus infection, congestion and headaches). Sinusitis is sometimes chronic (lasting for a very long time) and often comes back after being treated. The purpose of this study is to find an effective treatment for sinusitis in people with HIV infection, and to find a way to prevent it from coming back.

**About the study:**

Patients must be enrolled in this study while they are having an attack of sinusitis. Patients are treated with antibiotics for 21 to 42 days, and then are treated for 14 days with decongestants. Then, patients are assigned by chance one of four experimental treatments to designed prevent the sinusitis from coming back. The first group takes a decongestant by itself. The second group takes a decongestant and a nasal steroid. The third group takes a decongestant and an antibiotic. The fourth group takes a decongestant, a nasal steroid and an antibiotic. Neither the patients nor their doctors know which drug(s) are being taken until the study ends. The study lasts one to two years.

**Required:**

- HIV positive, ARC or AIDS
- sinusitis that keeps coming back, even after being treated
- three attacks of sinusitis within the past year for patients with more than 200 CD4 cells (T-cells)
- one attack of sinusitis within the past year for patients with less than 200 CD4 cells (T-cells)
- at least 12 years old

**Not allowed:**

- active substance abuse
- significant emotional illness or psychosis
- active infection with CMV or MAC

**Location:**

Kaiser San Francisco
Gretchen Van Raalte, RN
(415) 202-3480
(Kaiser health plan members only)

## 77. Taste Comparison: Product 7068, Product 7068-LCT

**Title:**

Acceptance of Product 7068 and Product 7068-LCT By AIDS and ARC Patients In An Outpatient Clinic.

**About the Study:**

This is a 20 minute taste test of two formulations of nutritional drinks. Participants are asked to judge appearance, flavor, sweetness, consistency, mouth feel, aftertaste and overall acceptance of the products. Patients are assigned by chance to taste the product(s) and do not know which they are tasting.

**Required:**

- AIDS or ARC

**Location:**

SFGH - GI Unit
Kristin Weaver, RN, MS
(415) 206-8822

## 78. *Cryptosporidium* Diarrhea Treatment: Azithromycin

**Title:**

Azithromycin in the Treatment of Cryptosporidiosis in Patients with AIDS

**Purpose:**

To find out if azithromycin is a safe and effective treatment for *Cryptosporidium* infection

**About the study:**

Patients are assigned by chance to take 900 mg. of azithromycin or placebo for 21 days. Then treatment assignments are switched for 21 days. Neither the patients nor their doctors know which is being taken at any given point in the study until the study ends. The study lasts six weeks.

**Required:**

- HIV positive, ARC or AIDS
- *Cryptosporidium* in the stool
- at least 18 years old

**Not allowed:**

- diarrhea not caused by *Cryptosporidium*
- taking any other drugs which act against *Cryptosporidium*
- liver or kidney disease
- may not take other experimental drugs within seven days before starting the study. For purposes of this study, drugs available under a Treatment IND are not considered experimental.
- taking any drugs intended to boost the function of the immune system
- taking cancer chemotherapy

**Location:**

Summit Medical Center
Adult Immunology Clinic
Jamie Carroll, RN
(510) 273-8200

## 79. *Cryptosporidium* Diarrhea Treatment: Paromomycin (Humatin®)

**Title:**

A Double-Blind, Placebo-Controlled, Randomized Trial of Paromomycin for Treatment of Cryptosporidiosis in HIV Seropositive Patients with AIDS or CD4 Counts Under 150

**Purpose:**

To find out if paromomycin (Humatin®) is helpful in treating diarrhea caused by *Cryptosporidium.*

**About the study:**

In the first part of the study, patients are assigned by chance to take Humatin® or placebo for 21 days. Neither the patients nor their doctors know which is being taken in this part of the study until the study ends. In the second part of the study, everyone takes Humatin® for 21 days. If people are still having problems with *Cryptosporidium* after 21 days of treatment, they take a higher dose of Humatin® for 21 more days. The study lasts up to three months.

**Required:**

- HIV positive, ARC or AIDS
- less than 150 CD4 cells (T-cells)
- diarrhea caused by *Cryptosporidium* (must be verified in two stool samples)
- at least four loose stools per day for at least four out of the last seven days before entering the study
- at least 13 years old

**Not allowed:**

- may not take any other drug which acts against *Cryptosporidium* within 14 days before entering the study
- active infection with any other organism which may cause diarrhea
- diarrhea caused by anything other than *Cryptosporidium*

**Location:**

Kaiser San Francisco
Gretchen Van Raalte, RN
(415) 202-3480
(Kaiser health plan members only)

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Many women think they can't join clinical trials. In fact, most trials are open to both men *and* women. There are also a few trials for women only. If you are a woman you may want to turn to page 63 for special information about women and clinical trials.

## 80. *Cryptosporidium* Diarrhea Treatment: Diclazuril®

**Title:**

Open Label, Compassionate Clearance Treatment of AIDS-Related Cryptosporidial Diarrhea with Diclazuril®

**Purpose:**

To make the drug Diclazuril® available to people with AIDS-related cryptosporidial diarrhea.
Diclazuril® is not yet approved for sale.

**About the study:**

Physicians must enroll patients through the drug company (Janssen). Patients are given a six-week supply of pills to be taken every day. Patients are seen by their doctor once a week for the first month and once a month thereafter. Patients may receive the medication for as long as they need it and it is helping.

**Required:**

- AIDS-related cryptosporidial diarrhea
- at least 3 watery bowel movements daily for a minimum of two weeks
- at least 12 years old

**Not allowed:**

- other investigational drugs (except expanded access or treatment IND)

**Location:**

Any health care provider can enroll eligible patients into this program by calling Janssen Research at (609) 730-3141. Ask your provider for details.

## 81. ddI-Associated Diarrhea: Two Different Formulations of ddI

**Title:**

An Open Label Randomized Comparison of the Incidence of Diarrhea with Videx® (ddI) Buffered Powder for Oral Solution and Videx® Chewable Dispersible Buffered Tablets

**Purpose:**

Stomach acid can break down ddI and stop it from working. The powdered form of ddI contains an antacid to lower the acidity of the stomach. But the antacid contained in the powdered form of ddI gives some people diarrhea. This study is trying to find out if using a different antacid with ddI has any effect on the amount or frequency of diarrhea in people who take it.

**About the study:**

All patients in this study take ddI. They are assigned by chance to take either ddI powder mixed with liquid or ddI chewable tablets. The study lasts seven weeks.

**Required:**

- AIDS or ARC
- unable to take AZT because of side effects, or HIV disease getting worse while taking AZT
- at least 18 years old

**Not allowed:**

- active opportunistic infection
- bowel disease
- diarrhea that is not caused by taking ddI
- current drug or alcohol abuse

**Location:**

San Francisco VA Medical Center
Sandy Charles, RN or Bill Stanton, RN
(415) 221-4810, Ext. 3763

## 82. Bronchitis Treatment: Cefuroxime, Augmentin

**Title:**

The Treatment of Bronchitis in the HIV-Infected Patient with Either Cefuroxime Axetil or Amoxicillin Clavulanate

**Purpose:**

To compare the effectiveness of two antibiotics, cefuroxime axetil and amoxicillin clavulanate (augmentin), in treating bacterial bronchitis in HIV-infected patients.

**About the study:**

Patients are assigned by chance to take either cefuroxime pills twice per day for 14 days or augmentin pills three times per day for 14 days. Including follow-up exams, the study lasts 28 days.

**Required:**

- HIV positive
- bacterial bronchitis
- at least 18 years old

**Not allowed:**

- active opportunistic infection or cancer (except stable Kaposi's sarcoma)
- evidence of pneumonia
- use of other antibiotics within 30 days [except a stable dose of trimethoprim / sulfamethoxazole (also called Septra® or Bactrim™ ) for PCP prophylaxis]

**Location:**

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

## 83. Measles Vaccine

**Title:**

The Immunogenicity and Safety of Measles Vaccine in Patients with HIV Infection

**Purpose:**

To find out if giving measles vaccine to people with HIV infection can prevent them from getting measles.

**About the study:**

Both HIV positive and HIV negative patients may enroll in this study. People with antibodies to measles and people without antibodies to measles may enroll. Everyone in the study is given one dose of measles vaccine, injected into a muscle. Blood tests two weeks, four weeks and three months after the vaccination measure the effects of the vaccine on the immune system. The study lasts three months.

**Required:**

- HIV negative, HIV positive, ARC or AIDS
- at least 18 years old

**Not allowed:**

- active infection
- fever above 101 degrees Fahrenheit
- allergy to eggs or neomycin
- receiving whole blood or immune globulin within two months before starting the study
- active untreated tuberculosis
- using any substance intended to boost the function of the immune system within four weeks before starting the study (such as interferon or GM-CSF)

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 84. Measles Vaccine

**Title:**

Immunogenicity of Live Attenuated Measles (Rubeola) Vaccine in Immunocompetent Persons (CCTG #533b)

**Purpose:**

To learn how the measles vaccine affects people who test positive for HIV and are at risk for measles.

**About the study:**

Patients have six blood tests, two before the vaccine is given, and four after the vaccine is given. All patients are asked to fill out a daily diary of any symptoms or side effects for three weeks after the vaccination. Patients are paid $25 for each blood test (total $150) and if they complete all six, an extra $50. The study takes about 6 to 8 weeks to complete.

**Required:**

- HIV positive
- blood test indicates risk for measles

**Location:**

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 85. Fungal Disease: Itraconazole

**Title:**

An Open Non-Comparative Study of the Efficacy of Itraconazole in Progressive Mycoses

**Purpose:**

To learn if itraconazole is effective against a number of serious fungal infections (especially *Aspergillus* species) which are resistant to other types of treatment.

**About the study:**

Everyone begins the study taking the same dose of itraconazole every day, in capsule form. Depending on response to treatment, the dose may be increased if necessary and if the drug is well-tolerated. The study lasts for one year.

**Required:**

- AIDS
- a serious fungal infection, especially *Aspergillus*, which has not gotten better with other types of treatment

**Location:**

Santa Clara Valley Medical Center
Dan Dewsnup, MD
John Hostetler, MD
David Stevens, MD
(408) 299-5587

If there are words or phrases in this book that you don't understand, you may be able to find explanations in the Glossary, starting on page 81.

## 86. Stress: Facilitated Education Groups

**Title:**

Positive Education Project

**Purpose:**

To learn if taking part in education groups can help gay men manage living with the stress of being HIV positive.

**About the study:**

Patients are assigned by chance to one of two groups or to a brief waiting list. One group focuses on information intended to help manage living with HIV. The other group focuses on how individuals react to the stress of being HIV positive. People on the waiting list will be assigned to a group after three months. Group members meet for ten weekly group sessions. Group members also answer a short set of questions and have blood tests several times during the course of the study. Group members take part in the study for one year. After a year, they may take part in a shorter version of the other group, if they wish.

**Required:**

- HIV positive, ARC or AIDS
- gay men between 21 and 60 years old
- 200 - 500 CD4 cells (T-cells)
- must not be receiving psychotherapy or taking psychoactive medications now

**Location:**

UCSF - Center for AIDS Prevention Studies
Derek Aspacher
(415) 597-9141

## 87. Stress: Observational Study

**Title:**

African American Men's Coping Project

**Purpose:**

To collect information about how African American men are coping with stress in their lives. To learn how to develop coping programs and mental health services for African American men who want help in dealing with stress.

**About the study:**

Men in this study are asked questions about stresses in their lives, how they cope with stress, and their moods. A physical exam is done and tests of memory and concentration are given. Blood is drawn for an HIV antibody test, and results and counselling are given. This takes a total of five hours, on two different days. People who take part in the study are paid $50.

**Required:**

- African American men only
- gay or bisexual men only
- must live in San Francisco
- have never used injection drugs
- may be HIV positive or HIV negative

**Location:**

UCSF - Prevention Sciences Group
Lee Middleton
(415) 597-9290

## 88. Effect of HIV on the Central Nervous System: Observational Study

**Title:**

CNS Effects of HIV: MR and Cognitive Studies

**Purpose:**

To learn how HIV infection affects the brain and central nervous system.

**About the study:**

Patients are given several kinds of tests; including blood tests, brain scans, written tests and interviews. Patients are paid a total of $135 for the study.

**Required:**

- men only
- may be HIV positive or negative
- at least 21 years old

**Not allowed:**

- active illegal drug use
- ever had a major head injury or epilepsy

**Location:**

San Francisco VA Medical Center
Nina Grossman
(415) 750-0812

There are many organizations that can help you learn more about HIV disease and about treatments for HIV disease. You may want to read the Resources section starting on page 77 for more information on these groups.

## 89. Anal Cancer: Observational Study

**Title:**

The Natural History of Anal Neoplasia in HIV-Infected Men

**Purpose:**

HIV infected men are at high risk of developing invasive anal cancer. The purposes of this study are: 1) To learn about the development and course of precancerous anal disease over time. 2) To learn about the role of certain viruses, immune system problems and other factors in the course of anal disease.

**About the study:**

At study entry and every six months thereafter, patients answer some questions and have an anal examination. Cultures are also taken. A biopsy may be performed if anything abnormal is found during the exam. If signs of precancerous disease of the anus develop, the patient is referred to a specialist for treatment. This study lasts four years.

**Required:**

- men only
- may be either HIV negative or HIV positive, any stage of disease

**Not allowed:**

- anyone who has been treated for anal cancer in the past

**Location:**

California Pacific Medical Center
David Jaramillo
476-2909

## 90. Heterosexual HIV Transmission: Observational Study

**Title:**

California Heterosexual Partner Study

**Purpose:**

To learn about the risks of heterosexual transmission of HIV and factors which influence transmission. To learn about beginning signs of illness in women.

**About the study:**

Everyone in this study is given a physical exam and blood tests, including a test for HIV. Counseling is given on HIV disease, HIV transmission and safer sex practices. Referrals are made to social, psychological and medical services. Study staff travels throughout Northern California to see participants.

**Required:**

- HIV positive and have had heterosexual contact *(or)*
- sexual partner of an HIV positive person

**Location:**

SFGH - Heterosexual Partner Study
Imani Ajaniku
1-800-262-2430 (English)
(510) 524-4985 (Spanish)

You may have heard that injection drug users can't be in clinical trials. The truth is, injection drug users are *not* always excluded from joining a clinical trial. See page 69 for more information about injection drug users and clinical trials.

## 91. Treatment of Yeast Infections (Fungal Infections) in Women: Fluconazole

**Title:**

A Randomized Trial of Two Different Dosages of Fluconazole in the Treatment of Vulvovaginal Candidiasis in Women with HIV Infection (CCTG #543)

**Purpose:**

To compare two doses of fluconazole for treatment of vaginal candidiasis (yeast infection).

**About the study:**

Patients are assigned by chance to one of two treatment groups. The first group takes 100 mg. of fluconazole per day for one week. The second group takes 200 mg. of fluconazole one time only. Neither patients nor their doctors know which dose is being taken until the study ends. The study lasts three months.

**Required:**

- HIV positive women only
- vaginal candidiasis (yeast infection)
- at least 12 years old

**Not allowed:**

- pregnant women
- may not take any other anti-fungal drugs while on this study

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 92. Prevention of Yeast Infections (Fungal Infections) in Women: Fluconazole

**Title:**

A Randomized, Prospective, Double-Blind Study Comparing Fluconazole With Placebo for Primary and Secondary Prophylaxis of Mucosal Candidiasis in HIV-Infected Women (CPCRA 010)

**Purpose:**

Infection with a fungus called *Candida albicans* is a common problem for women with HIV. *Candida* may cause problems in the mouth, esophagus or vagina. *Candida* infections are sometimes called yeast infections or thrush. The purpose of this study is to learn if taking fluconazole can prevent women with HIV from getting *Candida* infections.

**About the study:**

Patients are assigned by chance to take fluconazole pills or a placebo. Neither patients nor their doctors know which is being taken until the study ends. A physical exam, including a vaginal exam, will be given every three months. A complete pelvic exam will be given every six months. The study lasts two years.

**Required:**

- HIV positive women only
- CD4 cell (T-cell) count of 300 or below
- at least 13 years old

**Not allowed:**

- women who have already had *Candida* infection of the esophagus
- taking any other drug which acts against *Candida*

**Location:**

Community Consortium. Ask your health care provider (see page 75).

## 93. Prevention of Yeast Infections (Fungal Infections) in Women: Fluconazole

**Title:**

A Randomized Study of Daily and Weekly Prophylactic Fluconazole for the Prevention of Vulvovaginal Candidiasis in Women with HIV Infection (CCTG #554)

**Purpose:**

To find out if taking fluconazole can help prevent women from getting vaginal candidiasis (yeast infection). To compare the effectiveness of taking fluconazole every day or once per week to prevent yeast infections. To learn about the safety of taking fluconazole to prevent yeast infections.

**About the study:**

Patients are assigned by chance to take 50 mg. of fluconazole every day or 200 mg. of fluconazole once per week. Neither the patients nor their doctors know which dose is being taken until the study ends. The study lasts six months.

**Required:**

- women only
- at least two yeast infections within six months before starting the study *or* one yeast infection within ten days before starting the study
- at least 12 years old

**Not allowed:**

- taking any other drugs which might act against yeast infections
- unexplained fever

**Location:**

AIDS Community Research Consortium
Brian Camp, RN
Deborah Harriss, NP
(415) 364-6563

San Mateo County AIDS Program
Jeff Bubp, PharmD
(415) 573-2385
(415) 573-2588

Santa Clara Valley Medical Center
Carol Kane, RN
(408) 299-5523

## 94. GYN Screening: Pap Smears Versus Colposcopy

**Title:**

Papanicolaou (Pap) Smears Versus Colposcopy Screening Tests for Cervical Intraepithelial Neoplasia (CIN) in Human Immunodeficiency Virus (HIV) Seropositive Women

**Purpose:**

To compare the effectiveness of Pap smears and colposcopy for finding changes in the lining of the cervix which may be related to HIV disease.

**About the study:**

Patients are given three pelvic exams, including Pap smears and colposcopy. One exam is done at the start of the study, one six months later and one at the end of the study. The study lasts one year.

**Required:**

- HIV positive women only

**Location:**

East Bay AIDS Center
Deborah Norton, NP
(510) 204-1870

Highland General Hospital
Adult Immunology Clinic
Kathleen McCarthy, RN
(510) 437-4050

## 95. HIV Infection in Women: Vaccine Trial

**Title:**

Phase I Safety and Immunogenicity of MN rgp120/HIV-1 Vaccine (Genentech) in HIV-1 Infected Pregnant Women with CD4 Lymphocyte Counts $\geq 400 / mm^3$ (ACTG 235)

**Purpose:**

To find out if it is safe for pregnant women to take this experimental vaccine for HIV infection. To learn about the effects of the vaccine on the mother and baby.

**About the study:**

Patients are assigned by chance to receive injections of the vaccine or a placebo. Neither the patients nor their doctors know which is being given until the study ends. Five injections will be given during the course of the pregnancy, with an option for four more injections during the year after delivery. The study lasts until 18 months after delivery.

**Required:**

- pregnant women only
- between 16 and 40 years old
- HIV positive, but without symptoms of HIV disease
- at least 400 CD4 cells (T-cells)
- not known to be at high risk for pregnancy and delivery
- must receive first injection between 16th and 24th week of pregnancy

**Not allowed:**

- any signs of fetal abnormality
- active substance abuse
- taking any anti-HIV drug other than AZT within 90 days before starting the study
- active hepatitis B

**Location:**

SFGH - Bay Area Perinatal AIDS Center
(Ms.) Joel Miller
(415) 206-8919

## 96. HIV Infection in Women: Observational Study

**Title:**

Natural History Study of HIV Infection in Women

**Purpose:**

To learn more about changes in health status, drug use, and sexual and reproductive behavior in HIV positive women.

**About the study:**

Physical exams and laboratory tests are performed at six month intervals for as long as the study lasts (indefinite). Project AWARE staff also provides information and / or referrals about treatments, clinical trials and general health issues to women who take part in the study.

**Required:**

- HIV positive women

**Location:**

UCSF - Project AWARE
(415) 476-4091

## 97. HIV Infection in Women: Observational Study

**Title:**

Natural History of HIV Disease in Women and Access to Care

**Purpose:**

To learn more about how HIV infection affects women in different risk groups. To compare the ways in which HIV disease affects women and men. To learn about how and where women with HIV get their health care.

**About the study:**

Women who participate in this study are given an interview, a physical exam and a GYN exam every six months. Specimens are collected for culture during every exam. The study lasts two years.

**Required:**

- HIV positive women only
- must be a patient in the UCSF AIDS Clinic, Highland General Hospital Adult Immunology Clinic or East Bay AIDS Center, or be enrolled in the UCSF Partners Study or Project AWARE study
- at least 18 years old

**Location:**

Highland General Hospital
Adult Immunology Clinic
Kathleen McCarthy, RN
(510) 437-4050

## 98. HIV Infection in Pregnant Women and their Babies: AZT

**Title:**

A Phase III Randomized, Placebo-Controlled Trial to Evaluate the Efficacy, Safety and Tolerance of Oral Zidovudine (ZDV) in Pregnant HIV-Infected Women and their Infants (ACTG 076)

**Purpose:**

To find out if AZT is helpful in treating HIV infection in pregnant women and their babies. To find out if AZT helps prevent HIV from being passed from the mothers to their babies before birth.

**About the study:**

Patients are assigned by chance to take AZT or a placebo. Neither the patients nor their doctors know which is being taken until the study ends. Mothers are in the study until the baby is born. Babies stay in the study for up to five years. Hospitalization is required for delivery of the baby.

**Required:**

- HIV positive without symptoms of HIV disease
- CD4 cells (T-cells) greater than 200
- between 14th and 34th week of pregnancy
- mothers must be at least 13 years old

**Not allowed:**

- AIDS
- evidence of certain birth defects in the fetus

**Location:**

SFGH - Bay Area Perinatal AIDS Center
(Ms.) Joel Miller
(415) 206-8919

## 99. Mothers and Children with HIV: Observational Study

**Title:**

Natural History Study of Maternal and Infant AIDS

**Purpose:**

To learn more about HIV infection in pregnant women and young children. To learn more about transmission from mother to baby.

**About the study:**

Mothers and their babies are given physical exams and blood tests on a regular basis. Pregnant women are followed for pre-natal care and HIV care. After delivery, mothers are followed for GYN care and referred for primary care. Infants are followed for primary care. Patients are given the option to enroll in drug studies they are eligible for.

**Required:**

- HIV positive pregnant women *(or)*
- HIV negative pregnant women with current or past history of injection drug use *(or)*
- infants aged birth to five years whose mothers are enrolled in the study

**Location:**

SFGH - Bay Area Perinatal AIDS Center
(Ms.) Joel Miller
(415) 206-8919

## 100. HIV Infection in Children: AZT

**Title:**

A Phase III Study to Evaluate the Safety, Tolerance and Efficacy of Early Treatment with Zidovudine (ZDV, AZT) in Asymptomatic Infants with HIV Infection (ACTG 182)

**Purpose:**

To find out if giving AZT to very young children with HIV infection can help prevent them from getting symptoms of HIV disease. To find out if it is safe to give AZT to very young children who have HIV infection but who do not yet have symptoms of HIV disease.

**About the study:**

Infants are assigned by chance to take a liquid form of AZT or a placebo. Neither the infants, their parents nor their doctors know which is being taken until the study ends. Infants who develop more advanced symptoms of HIV disease will be allowed to take "open-label" AZT. This means that they will take the real drug, not a placebo.

**Required:**

- less than nine months old
- HIV positive, but without symptoms of HIV disease
- more than 2000 CD4 cells (T-cells)
- must weigh at least 2000 grams
- no serious, active infections

**Not allowed:**

- more than seven weeks of anti-HIV treatment before starting this study
- more than seven weeks of treatment intended to boost the function of the immune system before starting this study
- neurologic or neuropsychologic problems

**Location:**

Children's Hospital of Oakland
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3337

Stanford University Pediatrics Department
Barbara Sullivan, RN
(415) 723-5682

## 101. HIV Infection in Children: AZT, ddC

**Title:**

A Phase II Study to Evaluate Pharmacokinetics, Safety, Tolerance and Activity of Dideoxycytidine (ddC) Administered in Combination with Zidovudine (ZDV, AZT) in Stable, ZDV Treated Pediatric Patients with HIV Infection (ACTG 190)

**Purpose:**

To find out if it is safe to give a combination of the drugs AZT and ddC to children with HIV infection. To learn how the combination of AZT and ddC is absorbed and processed by the body. To compare the effectiveness of taking one anti-HIV drug or a combination of these drugs to treat HIV disease in children.

**About the study:**

Patients are assigned by chance to take AZT by itself or AZT and ddC together. Neither the patients nor their doctors know which is being taken until the study ends. The study lasts at least 32 weeks, with a possibility of two 32 week extensions.

**Required:**

- HIV positive
- three months to 12 years old
- must have taken AZT for at least six weeks before starting the study

**Not allowed:**

- unable to take AZT due to side effects
- anyone who has ever had pancreatitis
- anyone who has ever had peripheral neuropathy
- cancer that must be treated with chemotherapy

**Location:**

Children's Hospital of Oakland
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3337

Stanford University Pediatrics Department
Barbara Sullivan, RN
(415) 723-5682

UCSF - Pediatrics Department
Sharon Esker, RN
Estrella Manio, RN
(415) 476-9373

If you are between the ages of 13 and 18 you may not be sure where you "fit in" with clinical trials. You may be eligible for trials designed for either children or adults. If you are interested in joining a trial, special health care and support programs for youth can help you sort through the confusion. Pages 67 and 68 will help you get started.

## 102. HIV Infection in Children: AZT, ddI

**Title:**

A Randomized Comparative Trial of Zidovudine (ZDV) Versus 2',3'-Dideoxyinosine (ddI) Versus ZDV Plus ddI in Symptomatic HIV-Infected Children (ACTG 152)

**Purpose:**

To compare the safety and effectiveness of taking AZT alone, ddI alone, or AZT and ddI together for treatment of HIV infection.

**About the study:**

Patients are assigned by chance to take AZT, ddI, or AZT and ddI together for two years. All drugs are taken by mouth, in pill or powder form. Neither the patients nor their doctors know which is being taken until the study ends. Patients who have a bad reaction to the first drug assigned may switch to the other drug.

**Required:**

- HIV positive
- aged 3 months to 18 years
- for patients less than 15 months old, CD4 cell (T-cell) count less than 1000
- for patients older than 15 months, CD4 cell (T-cell) count less than 500 or growth failure or a persistent opportunistic infection

**Not allowed:**

- more than 6 weeks of antiretroviral therapy (AZT, ddI, ddC) at any time in the past
- any antiretroviral therapy within eight weeks of starting the study
- pancreatitis or peripheral neuropathy
- active drug or alcohol abuse

**Location:**

Children's Hospital of Oakland
Ann Petru, MD
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3337

UCSF - Pediatrics Department
Estrella Manio, RN
(415) 476-9373

Stanford University Pediatrics Department
Barbara Sullivan, RN
(415) 723-5682

## 103. HIV Infection in Children: ddI

**Title:**

A Randomized Comparative Trial of Two Doses of 2',3'-Dideoxyinosine (ddI) in Children with Symptomatic HIV Infection Who Are Either Unresponsive to Zidovudine and / or Are Intolerant to Zidovudine (ACTG 144)

**Purpose:**

To learn if the drug ddI is a safe and effective treatment for HIV disease for children who are not being helped by AZT, or who cannot take AZT due to side effects.

**About the study:**

Patients are assigned by chance to take one of two doses of ddI. Everyone in the study takes ddI, but neither patients nor their doctors know which dose is being taken until the study ends. The study lasts at least 48 weeks and, for some patients, as long as 96 weeks.

**Required:**

- AIDS or ARC
- at least three months old, but less than 18 years old
- unable to take AZT because of side effects, *or*
- HIV disease has gotten worse after taking AZT for at least six months

**Not allowed:**

- active opportunistic infection
- use of any other antiretroviral drug (except AZT or ddC) within four weeks of starting the study
- pancreatitis, peripheral neuropathy or uncontrolled seizures
- cancer that must be treated with chemotherapy

**Location:**

UCSF - Pediatrics Department
Sharon Esker, RN
(415) 476-9373

## 104. HIV Infection in Children: Vaccine Trial

**Title:**

A Placebo-Controlled, Phase I Trial to Evaluate Safety and Immunogenicity of Recombinant Envelope Proteins of HIV-1 GP-160 and GP-120 in Children with Asymptomatic HIV Infection (ACTG 218)

**Purpose:**

To find out if it is safe to give these experimental vaccines to children with HIV infection. To learn about the effects of these experimental vaccines on childrens' immune systems.

**About the study:**

Patients are assigned by chance to receive injections of one of the experimental vaccines or a placebo. Neither patients nor their doctors know which is being given until the study ends. One injection is given every four weeks, until a total of six injections have been given. Counting 24 weeks of follow-up after the last injection has been given, the study lasts about one year.

**Required:**

- HIV positive
- between one month and 12 years old
- no symptoms of HIV disease

**Not allowed:**

- may not take any anti-HIV drugs or drugs intended to boost the function of the immune system within four weeks before starting the study
- use of steroids for more than six weeks
- serious active infections

**Location:**

Children's Hospital of Oakland
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3337

Stanford University Pediatrics Department
Barbara Sullivan, RN
(415) 723-5682

UCSF - Pediatrics Department
Estrella Manio, RN
(415) 476-9373

**If there are words or phrases in this book that you don't understand, you may be able to find explanations in the Glossary, starting on page 81.**

## 105. PCP Prevention in Children: Dapsone

**Title:**

Comparison of Two Dosage Regimens of Oral Dapsone for Prophylaxis of *Pneumocystis carinii* Pneumonia in Pediatric HIV Infection (ACTG 179)

**Purpose:**

To find out if taking dapsone can help prevent PCP in children with HIV who cannot take trimethoprim / sulfamethoxazole (also called Septra® or Bactrim™). To compare the safety and effectiveness of two different doses of dapsone for preventing PCP. To learn more about how dapsone is absorbed and processed by the body.

**About the study:**

Patients are assigned by chance to take a low dose of dapsone every day or a higher dose once per week. The drug is taken by mouth. Everyone knows which dose is being taken, and how often. The study lasts at least three months.

**Required:**

- HIV positive children
- between the ages of one month and 12 years old
- cannot take trimethoprim / sulfamethoxazole because of side effects

**Not allowed:**

- any child who has taken dapsone in the past
- severe allergy to sulfa drugs
- may not take rifampin within one week before starting this study

**Location:**

Children's Hospital of Oakland
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3337

## 106. PCP Prevention in Children: Pentamidine

**Title:**

A Phase I / II Trial of Parenteral Pentamidine for PCP Prophylaxis in HIV-Infected Children Who Are Intolerant to Oral Trimethoprim-Sulfamethoxazole (ACTG 189)

**Purpose:**

To find out if taking pentamidine can help prevent PCP in children with HIV who cannot take trimethoprim / sulfamethoxazole (also called Septra® or Bactrim™). To compare the safety and effectiveness of two different doses of pentamidine for preventing PCP. To learn more about how pentamidine is absorbed and processed by the body.

**About the study:**

Patients are assigned by chance to take pentamidine every two weeks or once per month. Pentamidine is given by infusion into a vein. Everyone knows which dose is being taken, and how often. The study lasts at least six months.

**Required:**

- HIV positive children
- between the ages of one month and six years old
- cannot take trimethoprim / sulfamethoxazole because of side effects

**Not allowed:**

- pancreatitis

**Location:**

Children's Hospital of Oakland
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3337

# Drug Assistance Programs

## Sponsored by Pharmaceutical Companies

Some pharmaceutical companies have programs that provide drugs free to patients who could not otherwise pay for them. Each program has specific requirements about who is eligible and what kind of financial help is available. If you need help paying for any of the drugs listed below, talk to your doctor. He or she will need to call the coordinators of the appropriate program(s) and give them information about your financial status and prescription drug needs.

| Name of Drug | What Drug is Used For | Company and Name of Program | Telephone |
|---|---|---|---|
| Rifabutin<br>(Mycobutin®) | MAC disease prevention | **Adria Laboratories**<br>Mycobutin® Patient Assistance Program | 800-795-9759 |
| Foscarnet<br>(Foscavir®) | CMV disease,<br>acyclovir-resistant herpes simplex | **Astra Pharmaceuticals**<br>Foscavir® Assistance and Information on Reimbursement | 800-488-3247 |
| ddI<br>(Videx®) | HIV infection | **Bristol-Myers Squibb Co.**<br>Videx® Reimbursement Assistance and Temporary Assistance Programs | 800-788-0123 |
| AZT<br>(Retrovir®) | HIV infection | **Burroughs Wellcome Co.**<br>HIV Patient Assistance Program | 800-722-9294 |
| Trimethoprim / sulfamethoxazole<br>(Septra®)<br>(Bactrim™) | PCP prevention,<br>acute PCP | **Burroughs Wellcome Co.**<br>HIV Patient Assistance Program<br>**Hoffman-La Roche, Inc.**<br>Oncoline (Reimbursement Assistance) | 800-722-9294<br>800-443-6676 |
| Atovaquone<br>(Mepron®) | PCP treatment | **Burroughs Wellcome Co.**<br>HIV Patient Assistance Program | 800-722-9294 |
| Pyrimethamine<br>(Daraprim®) | Toxoplasmosis | **Burroughs Wellcome Co.**<br>HIV Patient Assistance Program | 800-722-9294 |
| Acyclovir<br>(Zovirax®) | Herpes simplex,<br>herpes zoster | **Burroughs Wellcome Co.**<br>HIV Patient Assistance Program | 800-722-9294 |
| Aerosolized Pentamidine<br>(Nebupent®) | PCP prevention | **Fujisawa Pharmaceuticals**<br>Nebupent® Reimbursement Service | 800-366-6323 |

# Drug Assistance Programs

## Sponsored by Pharmaceutical Companies

| Name of Drug | What Drug is Used For | Company and Name of Program | Telephone |
|---|---|---|---|
| ddC<br>(Hivid®) | HIV infection | **Hoffman-La Roche, Inc.**<br>Assist Program (ddC) | 800-285-4484 |
| Interferon alfa-2b, recombinant (Roferon-A®) | Kaposi's sarcoma (more than 200 T-cells), anogenital neoplasms | **Hoffman-La Roche, Inc.** | |
| | | Oncoline (Reimbursement Assistance) | 800-443-6676 |
| | | Cost Assistance Program | 800-227-7448 |
| | | Indigent Patient Program | 800-529-6367 |
| Interferon alfa-2a, recombinant (Intron® A) | Kaposi's sarcoma (more than 200 T-cells), anogenital neoplasms | **Schering-Plough Corp.**<br>Interactive Reimbursement Information Services | 800-521-7157 |
| Erythropoietin<br>(Procrit®) | AZT-related anemia | **Ortho Biotech** | |
| | | Protocritline (Reimbursement Assistance) | 800-553-3851 |
| | | Cost Sharing Program | 800-441-1366 |
| | | Financial Assistance Program | 800-447-3437 |
| Fluconazole<br>(Diflucan®) | Fungal infections (cryptococcal meningitis, esophageal candidiasis, etc.) | **Pfizer Inc.**<br>Diflucan® Patient Assistance Program | 800-869-9979 |
| Ganciclovir<br>(Cytovene®) | CMV disease | **Syntex Laboratories**<br>Provisional Assistance Programs | 800-444-4200 |

This list was compiled by David Strickland. Reprinted with permission from *BETA* (*see* SanFrancisco AIDS Foundation, page 79).

# Common Questions

## About Clinical Trials

**What is a clinical trial?**

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial.

The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

**Why should I join? What do I get out of this?**

Here are some of the reasons to join a clinical trial:

- The treatment being tested may work for you.
- Clinical trials may be the only way to get a promising new drug.
- Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available on the "underground," or by prescription, you may not be able to afford it).
- You can help speed the development of new treatments for HIV.

**Will I be used as a "guinea pig"?**

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time.

In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that it may prevent you from getting sick.

**What if the drug makes me sicker?**

The researchers who design the trials always plan for what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

**Will I have to take a placebo ("sugar pill")?**

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled" study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug or would have happened without treatment.

Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

**How can I tell which trial might be good for me?**

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

**What are my rights as a patient?**

The people involved in your care must treat you with consideration and respect. You have the right to:

- be told all the important details about your care
- ask questions and have them answered
- say no to any test, procedure or medication
- go to another health care provider to get more information
- know the names of anyone you talk with
- read your medical records with your health care provider
- make your own decisions about your health care
- know that your medical records will be kept confidential

**What are my responsibilities as a patient?**

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- be honest about your medical history and anything in your lifestyle which may affect your health
- follow instructions and take the study drug(s) as requested
- keep appointments or re-schedule them at least 24 hours in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

### What is informed consent?

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving *informed consent.*

When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

### What should I know before I sign the consent form?

Before you sign the consent form, you should know:

- the reasons for using the experimental treatment
- the risks and benefits of taking part in the study
- any extra costs, doctor visits, lab tests, etc.
- what drugs you will have to take

### Are there any other questions I should ask before I sign the consent form?

Before you decide to join a trial, you may want to know:

- How will information about me be handled to protect my privacy?
- Can I take the drug after the trial is over? Will I have to pay for it?
- If I get sick or develop health problems while on the trial, will I be taken off the trial?
- How can I find out the results of the trial?
- Are there other studies of this drug I should know about?
- (For women) Do I have to use birth control? If so, what kind? If I become pregnant will I have to leave the study?

### What should I do If I don't understand something?

*Do not sign the consent form until you understand everything in it.* Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions.

# How to Enroll in a Clinical Trial

### Getting more information about specific studies

If you want to find out more about a specific clinical trial, call the person listed under "Location" for that trial. This is usually a research nurse or study coordinator. S/he will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

### Finding out if you're eligible: The screening visit

If the research nurse thinks you may be eligible, s/he will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

### Giving "informed consent"

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join.

### The first study visit

After you have signed the consent form, you can join the study during a "baseline" visit, the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

### Followup visits

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects you may be having. If everything seems to be all right, you will be asked to come back for regular followup visits. Frequency of visits may vary from daily to every few months, depending upon the study.

### Keeping in touch

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

# Women and Clinical Trials

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

## Can women with HIV join clinical trials?

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men.

Women often don't get enough information about clinical trials and think that they cannot join simply because they are women.

## Are there special rules about birth control and pregnancy?

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

## What happens if a woman becomes pregnant while in a trial?

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant. Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion.

If you become pregnant, you may want to talk to the Bay Area Perinatal AIDS Center (BAPAC) at San Francisco General Hospital. They can give you the most current information about pregnancy and HIV disease.

You may call BAPAC at (415) 821-8919.

# Children
## and Clinical Trials

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older.

Children's research is done by doctors and nurses who are experts in children's bodies and health.

### Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in a child. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

### Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called *"informed consent"* (see page 59).

### Where can I find out more about clinical trials for children with HIV?

In the Bay Area, there are several places where you can get information about children with HIV and clinical trials. This directory lists trials for children beginning on page 50. Please also see page 63 for information on Women and Clinical Trials.

**Where can children with HIV get health care or join a clinical trial?**

Bay Area Perinatal AIDS Center
San Francisco General Hospital
Ms. Joel Miller
(415) 206-8919

Provides medical care for pregnant women with HIV and their unborn children, and for mothers with HIV and their babies.

Children’s Hosptial of Oakland
Department of Pediatrics
Ann Petru, MD
Jim Riddel, RN
Karen Szajkowski, RN
(510) 428-3336

Conducts clinical trials for children with HIV. Experts in medical care for children with HIV.

Stanford University Medical Center
Department of Pediatrics
Barbara Sullivan, RN
(415) 723-5682

Conducts clinical trials for children with HIV. Experts in medical care for children with HIV.

University of California, San Francisco
Department of Pediatric Immunology
Debbie Trevithick
(415) 476-6480

Conducts clinical trials for children with HIV. Experts in medical care for children with HIV. Their Community Advisory Board (CAB) allows people from the community, including parents of children with HIV, to have a say in the research that is done.

**What are some other resources for children?**

Bridge for Kids
1387 Oak Street
San Francisco, CA 94117
(415) 552-2437

Provides free childcare for children with HIV, and for children whose parents have HIV. English and Spanish speaking.

# Youth
## and Clinical Trials

### What does "youth" mean?

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

### Why are youth treated differently in clinical trials?

Youth are different physically and emotionally from both children and adults. Healthcare and support programs for youth take these differences into account.

### Are there special clinical trials for youth?

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both children's and adults' clinical trials. We list age restrictions for all the trials in this directory. There is a program in San Francisco called the **Adolescent HIV Clinical Trials Project** that helps youth who may want to join a clinical trial.

There are other programs to provide healthcare and support for youth with HIV. These are listed on the next page.

### Do youth need permission to join a clinical trial?

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial. Even if you get medical care at a clinic without permission, you usually cannot join a trial without your parents' or guardians' consent. There are people working to change the laws in this area, and they may be able to help you join a trial without your parents' permission in certain situations. See page 59 for an explanation of what it means to give *"informed consent."*

### Where can I get more information about clinical trials for youth?

**Adolescent HIV Clinical Trials Project**
Becky Perelli, RN-C
(415) 753-7869

This is a new project that helps young people with HIV who may want to join a clinical trial. The staff are experts in the medical and social needs of youth,especially youth with HIV. They work closely with family and other service providers, if necessary. Services are free.

### Where can I go for health care?

**Huckleberry House / Cole Street Clinic**
555 Cole Street, #5 (at Haight Street)
(415) 751-8181

Free medical and support services.

**Larkin Street Medical Clinic**
1044 Larkin Street (at Sutter Street)
(415) 673-0911

Free medical and support services for homeless and runaway youth ages 12 to 23.

**Youth Guidance Outpatient Services**
375 Woodside Avenue (at Portola)
(415) 753-7764

Free medical and support services.

**UCSF Teen Clinic**
400 Parnassus, 2nd Floor, Room A270
(415) 476-8626 (Dave Knopf)

Full medical and support services.

**San Francisco General Hospital**
1001 Potrero Avenue (between 22nd and 23rd Streets)
Adolescent Clinic (under 18 years old) (415) 206-8376
STAR Services (18 to 21 years old) (415) 206-8436

Free medical and support services.

**Kaiser Teenage Clinic**
2540 Geary Boulevard, 1st Floor (near Divisidero)
(415) 202-2213

Medical and support services for youth who have Kaiser insurance or MediCal.

### What other kinds of services are available for youth with HIV?

There are many programs in San Francisco for youth with HIV. You can get a full listing from Project AHEAD.

**Project AHEAD**
Ron Henderson
(415) 753-7786

Provides coordination of HIV support services, counseling and testing, legal services, and housing for youth and their families.

# Injection Drug Users
## and Clinical Trials

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory *do not* exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial.

### Damaged liver or kidneys

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the "screening" visit. If any of the tests are "outside normal limits," you may not be able to join the trial. This is done to protect your health.

### Dangerous drug interactions

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know *every* drug you are taking, to prevent harmful side effects.

### Unable to comply with the "rules" of the study

Some trials have very complicated rules, and some people find it hard to follow them.That is why, if your doctor thinks you are "unreliable," you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.

# List of Clinical Trials Sites

**AIDS Community Research Consortium**
1048 El Camino Real, Suite A
Redwood City, CA 94063
(415) 364-6563

**Bay Area Perinatal AIDS Center (BAPAC)**
San Francisco General Hospital
1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110
(415) 206-8919

**California Pacific Medical Center - HIV Center**
3700 California Street, East Campus, 5th Floor
San Francisco, CA 94118
(415) 750-6529

**Calfornia Pacific Medical Center - Kuzell Institute**
2200 Webster Street, R305
San Francisco, CA 94115
(415) 561-1734

**Children's Hospital of Oakland - HIV Program**
747 - 52nd Street
Oakland, CA 94609
(510) 428-3337

**City Clinic (San Francisco Dept. of Public Health)**
356 - 7th Street
San Francisco, CA 94103
(415) 864-8100

**Community Consortium**
(See page 71 for list of participating sites and providers)
(415) 476-9554

**Davies Medical Center - HIV Institute**
Castro and Duboce Streets
San Francisco, CA 94114
(415) 565-6058

**East Bay AIDS Center**
3031 Telegraph Avenue, Suite 235
Berkeley, CA 94705
(510) 204-1870

**HemaCare Corporation**
450 Sutter Street, Suite 1504
San Francisco, CA 94108
(415) 399-0971

# List of Clinical Trials Sites

**Highland General Hospital - Adult Immunology Clinic**
1411 East 31st Street
Oakland, CA 94602
(510) 437-4050

**Kaiser Permanente Medical Center - HIV Research Unit**
2590 Geary Boulevard
San Francisco, CA 94115
(415) 202-3480

**Kaiser Permanente Medical Center**
280 West MacArthur Boulevard
Oakland, CA 94611
[call Kaiser SF at (415) 202-3480 for HIV Research Information]

**Kaiser Permanente Medical Group**
1635 Divisadero Street, Suite 360
San Francisco, CA 94115
(415) 929-2844

**Lifesource / NSM Research**
1635 Divisidero Street, Suite 135
San Francisco, CA 94115
(415) 749-6440

**Marcus A. Conant, MD Clinical Research**
1635 Divisidero Street, Suite 601
San Francisco, CA 94115
(415) 923-0555

**Marin County Specialty Clinic**
250 Bon Air Road
Greenbrae, CA 94904
(415) 499-7377

**Mt. Zion Medical Center - HIV Clinical Research Center**
1600 Divisidero Street
San Francisco, CA 94115
(415) 476-6356

**Saint Francis Memorial Hospital - HIVCare**
900 Hyde Street
San Francisco, CA 94109
(415) 775-4321

**San Francisco General Hospital - AIDS Research Group**
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
(415) 476-9296

**San Francisco General Hospital - GI Clinic**
1001 Potrero Avenue, Room 3C
San Francisco, CA 94110
(415) 206-8822

**San Francisco General Hospital -
Koret Center For Human Nutrition**
1001 Potrero Avenue, Building 40, Room 4101
San Francisco, CA 94110
(415) 206-4090

**San Francisco General Hospital - Tuberculosis Clinic**
1001 Potrero Avenue, Building 90, Ward 94
San Francisco, CA 94110
(415) 206-8524

**San Mateo County AIDS Program**
3700 Edison Street
San Mateo, CA 94403
(415) 573-2588

**Santa Clara County Health Department**
Early Intervention Project
976 Lenzen Avenue
San Jose, CA 95126
(415) 364-6563

**Santa Clara Valley Medical Center**
AIDS Research Annex, Room 108
751 South Bascom Avenue
San Jose, CA 95128
(408) 299-5523

**Stanford University Medical Center**
AIDS Clinical Trials Group
300 Pasteur Drive, Room S-156
Stanford, CA 94305
(415) 723-6231

**Stanford University Medical Center**
Department of Pediatric Infectious Diseases
300 Pasteur Drive, Room A-367
Stanford, CA 94305
(415) 723-5682

**Summit Medical Center - Adult Immunology Clinic**
3100 Telegraph Avenue, Third Floor
Oakland, CA 94609
(510) 273-8200

# List of Clinical Trials Sites

University of California San Francisco - AIDS Clinic
400 Parnassus Avenue, Fifth Floor
San Francisco, CA 94143
(415) 476-3226

University of California San Francisco -
Center for AIDS Prevention Studies (CAPS)
74 New Montgomery Street, Suite 600
San Francisco, CA 94105
(415) 597-9141

University of California San Francisco -
Prevention Sciences Group
74 New Montgomery Street, Suite 502
San Francisco, CA 94105
(415) 597-9290

University of California San Francisco - Project A.W.A.R.E.
(Association for Women's AIDS Research & Education)
3180 - 18th Street, Suite 205
San Francisco, CA 94110
(415) 476-4091

University of California San Francisco - Pediatric HIV Unit
505 Parnassus Avenue, Room M679
San Francisco, CA 94143
(415) 476-9373

Veterans Administration Medical Center
4150 Clement Street
San Francisco, CA 94121
(415) 221-4810, ext. 3763

ViRx, Inc.
655 Sutter Street, Suite 600
San Francisco, CA 94102
(415) 474-2233

# Community Consortium

## Sites and Providers

The Community Consortium conducts clinical trials at more than 20 sites in the San Francisco Bay Area. Health care providers who are participating in the Consortium's clinical trials program are listed at right. If you are interested in enrolling in a Consortium clinical trial and your health care provider is listed here, you can discuss enrollment during your next office visit. If your provider is not listed, encourage him or her to call the Consortium office at (415) 476-9554 for information about our clinical trials program.

### San Francisco -- Private Practices

Campbell, James, MD
Kaiser, Jon, MD
Krampf, Walter, MD
Mass, Martin, MD
Mills, Kenneth, MD
Owen, William, MD

### San Francisco -- Clinics and Hospital-Based Practices

**Health Center #1**

Alverio, Nilda, MD
Bailowitz, Jane, MD
Brown, Deborah, MD
Dyner, Toby, MD
Krampf, Walter, MD
Price, Lawrence, MD
Strauss, Fred, MD
Underwood, Ron, MD

**Kaiser Permanente - San Francisco**

Fessel, Jeffrey, MD

**Lyon-Martin Women's Health Svcs.**

Washington, Donna, MD

**Mission Neighborhood Health Ctr.**

Smith, James, DO
Vazquez, Robert, MD

**Mt. Zion Hospital**

Cafaro, Virginia, MD
Clark, Tina, NP
Drew, Lawrence, MD
Lalezari, Jay, MD
Mintz, Lawrence, MD

**Native American Health Center**

Pakula, John, MD

**St. Mary's Hospital and Med. Ctr.**

Bouvier, Denis, DO
Clarke, Jessica, MD, PhD
Etienne, Renee, NP
Weisberg, Ray, MD

**SFGH AIDS Clinic (Ward 86)**

Abrams, Donald, MD
Bayle, Karen, MD
Carr, Gary, NP
Cooke, Molly, MD
Harris, Nancy, MD
Jacobson, Mark, MD
Legg, Jill, MD
Lyons, Catherine, NP

**SFGH AIDS Clinic (continued)**

Moy, Alexander, MD
Murphy, Edward, MD
Strauss, Laura, PA
Wlodarczyk, Daniel, MD

**SFGH Early Intervention Clinic**

DePerez, Rosemary, NP

**SFGH General Medicine Clinic**

Fine, Richard, MD

**SFGH Ward 93**

Batki, Steve, MD
Bayle, Karen, MD
Ryan, Carol, NP

**Southeast Health Center**

Miller, Doriane, MD
Starks, Jay, MD
Wlodarczyk, Daniel, MD
Yatabe, Kay, MD

**UCSF AIDS Clinic**

Cosby, Cecily, NP, PA-C
Gifford, Allen, MD
Hollander, Harry, MD
Tokumoto, Jason, MD

### East Bay -- Private Practices

Jacobson, Susan, MD
Mayberry, Carl, PA-C
Scott, Robert, MD

### East Bay -- Clinics and Hospital-Based Practices

**Adult Hemophilia Clinic**
(Alta Bates-Herrick Hospital)

Lewis, Brad, MD

**East Bay AIDS Center**

Borkert, Claire, MD
Brosgart, Carol, MD
Feldman, Gary, MD
Jacobson, Susan, MD
Rose, Muriel, PA

**Highland Hosp. AIDS Clinic**

Borkert, Claire, MD
Clanon, Kathleen, MD
Morris, Bea, PA
Towner, Barbara, MD

### North Bay

Estes, Milton, MD

# Resources

If you need more information about drugs and other treatments for HIV and AIDS, there are a number of groups in San Francisco that can help. Many of the people who are involved in these organizations are also living with HIV and have learned a great deal about the disease. They can help you learn, too, so you can fight it more effectively.

**ACT-UP Golden Gate Chapter / Treatment Issues Committee**

Political action group. Committee works to reform treatment and drug development priorities and revolutionize the health care delivery system. Many members are very HIV knowledgeable.

Phone: (415) 252-9200 Information & announcements
(415) 252-9275 Office

Address: 519 Castro Street
San Francisco, CA 94114

**AIDS Treatment News**

Newsletter reporting on treatments for AIDS and public policy issues. Published twice a month. Subscription fee (available free or at low cost for people with limited income). Call for information. Highly respected.

Phone: (800) TREAT-1-2
(415) 255-0588

Address: P.O. Box 411256
San Francisco, CA 94141

**Bay Area Perinatal AIDS Center (BAPAC)**

Center at San Francisco General Hospital that studies transmission of AIDS from pregnant women to their unborn children. Good source of information about women with AIDS and pregnancy.

Phone: (415) 206-8919

Address: 1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110

**Drug Information and Clinical Trial Hotline**

Free national hotline, in English and Spanish, for information about AIDS Clinical Trials. Hours are Monday through Friday, 6:00am - 4:00pm (California time).

Phone: 1-800-874-2572 (1-800-TRIALS-A)

**EACH (Early Advocacy and Care for HIV)**

Early intervention for HIV and treatment advocacy services. Referrals to HIV testing sites, support groups, clinical trials, alternative treatments, and other social services for gay men of color. Spanish and Chinese speaking staff. Free.

Phone: (415) 403-3800

Address: 944 Market Street, Suite 210
San Francisco, CA 94102

**Gay / Lesbian Medical and Dental Referral Service**

Health care referrals for the gay and lesbian community. Provides referrals for medical, dental and chiropractic care.

Phone: (415) 673-3189

**Healing Alternatives Foundation**

"Buyers Club" for products aimed at improving the health of HIV positive people and people with AIDS, including vitamins, minerals, herbals, nutritional supplements, experimental substances, foreign products and more. Good resource and information library to encourage client participation in their health care program. Library is free, Buyers Club costs $1.00 to join. Open 12:00 to 6:00 pm, Tuesday through Friday; 12:00 to 5:00pm Saturday.

Phone: (415) 626-2316

Address: 1748 Market Street
San Francisco, CA 94102

**Mission Neighborhood Health Center, La Clínica Esperanza**

General medical care, clinical trials and social services for the Latino/a community. Bilingual (Spanish / English) staff.

Phone: (415) 431-3212

Address: 240 Shotwell Street
San Francisco, CA 94110

### Project Inform

Town Meetings for information about and discussion of treatments. Held twice a month. Information sheets and newsletter about available experimental drugs in treating AIDS, ARC, and HIV infection. Researches and disseminates information about where and how to obtain experimental drugs, current pricing, and what is known about dosage and clinical trials. California Hot-line. Free, donations for information sheets and newsletters accepted. Very knowledgeable staff.

Phone: (800) 334-7422 (California only)
(415) 558-9051

Address: 1965 Market Street
San Francisco, CA 94103

### San Francisco AIDS Foundation

Information and referrals to AIDS service organizations for people who need emotional or practical support. Spanish and Tagalog speaking staff. Publishes **BETA, the Bulletin of Experimental Treatments for AIDS. BETA** is published four times a year and has very up to date information on various aspects of HIV infection.

Phone: (415) 863-AIDS (Local)
(800) 367-AIDS (English & Spanish hotline)
(800) FIL-AIDS (Tagalog hotline)
(415) 863-2437 (for **BETA** subscription information, inside San Francisco)
(800) 327-9893 (for **BETA** subscription information, outside San Francisco)

Address: 25 Van Ness Avenue
San Francisco, CA 94102-6182

### Trials Search

Provides an individualized computer listing of available Bay Area clinical trials based on a two-page questionnaire (see page 87). Sliding scale fee: $0 to $7.00. Knowledgeable staff.

Phone: (415) 565-6368

Address: Davies Medical Center
Castro & Duboce Streets
San Francisco, CA 94114

**Acquired Immunodeficiency Syndrome (AIDS):** failure of the immune system believed to be caused by infection with the human immunodeficiency virus (HIV). The virus infects the body's cells that are essential to the proper functioning of the immune system.

**Adverse reaction ("side effect"):** toxic reaction due to experimental medicines. Common adverse reactions include rash, headaches, nausea, vomiting and drowsiness; and can be as severe as anemia, seizures and liver or kidney failure.

**AIDS-Related Complex (ARC):** a stage of HIV infection marked by symptoms such as swollen lymph glands (lymphadenopathy), chronic night sweats, recurrent fevers and unusual weight loss. Also commonly described as symptomatic HIV-infection.

**Antibacterial:** a substance which stops the growth of bacteria.

**Antibiotic:** a substance which kills or inhibits the growth of disease causing organisms, such as bacteria and fungi. For example, penicillin for some bacteria, amphotericin B or nystatin for some fungi.

**Antibody:** a protein produced by plasma cells in response to a specific antigen. Antibodies bind to antigens, often resulting in the inactivation of the antigen itself or the organism to which the antigen is attached. *See also* Antigen.

**Antifungal:** a substance which kills or inhibits the growth of a fungus.

**Antigen:** a substance, especially a protein, which stimulates production of antibodies.

**Antiretroviral:** a substance that stops or suppresses the activity of a retrovirus (for example, AZT, ddI, ddC). HIV is a retrovirus.

**Antiviral:** a substance that stops or suppresses the activity of a virus (for example, acyclovir, ganciclovir, foscarnet).

**ARC:** (abbreviation) *see* AIDS-Related Complex.

**Asymptomatic:** infection without symptoms. Someone may have HIV disease without showing any symptoms.

**AZT intolerant:** someone who has severe side effects when taking AZT and cannot continue taking it.

**Biopsy:** removal of a small amount of tissue from the patient, either surgically or with a small needle, for microscopic examination to determine if disease is present.

# Glossary

**Blinding:** in research, refers to the process of preventing patients and / or their doctors from knowing whether the patient is taking active drug or placebo. *See also* Double-blind.

**Bone marrow:** soft tissue in the interior of a bone where blood cells are produced.

**Bronchoscopy:** examination of the bronchi (lung passages) with the aid of a bronchoscope (a tube inserted into the lungs).

***Candida*:** a white, patchy fungus which often grows in the mouth or esophagus of people with AIDS, causing pain or difficulty in swallowing. Infection with *Candida* is known as "candidiasis" or "thrush."

**CD4 cell:** *see* T-cell

**Central nervous system (CNS):** the brain and spinal cord.

**Clinical trial:** a study which tests experimental medicines in human beings.

**CMV:** (abbreviation) *see* Cytomegalovirus.

**Combination therapy (for AIDS):** the use of two or more types of treatment in combination (for example, an antiviral therapy with an immunomodulator).

**Compassionate use:** an FDA program that makes certain experimental drugs available to seriously ill people when no other treatment exists or when the patient cannot tolerate other treatments.

**Cryptococcal meningitis:** a fungal infection caused by *Cryptococcus neoformans* that affects the three membranes (meninges) surrounding the brain and spinal cord. Symptoms include severe headache, dizziness, nausea, loss of appetite, vision disorders and mental deterioration.

**Cytomegalovirus (CMV):** a virus that can cause aching, fever, mild sore throat, fatigue and enlarged lymph nodes. In AIDS, severe CMV infections can produce hepatitis, pneumonia, retinitis and colitis, leading in some cases to blindness, chronic diarrhea and death.

**Diagnosis:** determining the cause and nature of an illness.

**Dose-ranging:** drug trial in which different doses of a given drug are compared in order to determine which dose is the most effective and the least toxic.

**Double-blind (double-masked):** trial procedure in which neither experimental subjects nor doctors know which subjects are receiving the test drug and which are receiving a placebo or other therapy. This method is believed to promote faster and more objective results, as doctors' and patients' opinions about a test drug's efficacy might otherwise bias test results.

**Efficacy:** a drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the FDA-mandated procedure, Phase II clinical trials gauge efficacy; Phase III trials confirm it.

**Encephalitis:** inflammation of the brain.

**Expanded access:** (also called "parallel track") a procedure extablished by the FDA which permits the use of investigational drugs by individual physicians. The purpose of this program is to make the drug available to patients who need it, while collecting at least some limited data on efficacy and toxicity.

**Experimental drug:** a drug that is being tested for use as a treatment for a specific condition in a specific population.

**Herpes:** 1) a group of viruses including herpes simplex I (HSV I), herpes simplex II (HSV II), varicella zoster, Epstein-Barr virus, and cytomegalovirus. 2) a common name for blisters on the mouth or genital regions caused by herpes simplex I and II.

**HIV:** (abbreviation) *see* Human Immunodeficiency Virus.

**HIV positive:** having antibodies to the human immunodeficiency virus in the body. Implies infection with HIV.

**Human Immunodeficiency Virus:** a slow-acting retrovirus which many people believe to be the sole or foremost causative agent of AIDS and ARC.

**Immune Thrombocytopenic Purpura (ITP):** an autoimmune disease, common in people with AIDS, in which the destruction of platelets (thrombocytes) leads to an increased susceptibility to bruising and bleeding.

**IM:** Intramuscular; injected into the muscle.

**Immunomodulator (also called a biological response modifier):** a drug which alters, suppresses or strengthens the immune system.

**IND:** (abbreviation) *see* Investigational New Drug.

**Infusion:** the process of giving a substance (medication, food supplements, etc.) to a patient by injecting it into the blood stream. This procedure can either be a one-time event or continued over many hours, days or even months.

**Intramuscular (IM):** injected into a muscle.

**Intravenous (IV):** injected into a vein.

**Investigational New Drug (IND):** term applied to an experimental drug after the FDA OKs testing the drug in people.

**ITP:** *see* Immune Thrombocytopenic Purpura.

**IV:** Intravenous; injected into a vein.

**Kaposi's sarcoma (KS):** an abnormal proliferation of small, poorly formed blood vessels which occurs in some people with AIDS. KS lesions may first appear anywhere on the body or in the soft palate of the mouth; they may also remain hidden in the internal organs. Temporary spots, whose blood can be easily pushed out by manual pressure, are not KS lesions.

**Lesion:** a change in tissue caused by disease. A point or localized patch of a skin disease. Other words that mean about the same thing as lesion include "sore" or "spot."

**Lumbar puncture (LP):** insertion of a needle into the spinal column to remove spinal fluid or to inject anesthesia or medicine.

**Lymphadenopathy:** swollen, firm and possibly tender lymph glands. Causes may range from a temporary infection (such as the flu) to lymphoma.

**Lymphoma:** a malignancy (cancer) of lymphocytes, the cells that are responsible for normal immune function.

**MAC (also called MAI):** (abbreviation) *see Mycobacterium avium-Intracellulare* Complex.

**Maintenance therapy:** use of a treatment to maintain a desired effect that has already been achieved.

**Malignant:** used to describe cells or tumors growing in an uncontrolled fashion, either spreading to other sites through the blood stream or invading nearby, normal tissues. By definition, cancers are always malignant, and the term "malignancy" implies a cancer.

***Mycobacterium avium-Intracellulare* Complex (MAC):** in people with AIDS, an infection which begins in the gut or lungs and is similar to tuberculosis. Later, the infection often spreads to other organs by way of the blood stream.

**Neoplasm:** tissue that grows more rapidly than normal; a tumor or growth. A neoplasm that does not spread to other tissues is described as benign. A neoplasm that spreads (metastasizes) to other tissues is termed malignant, and is commonly called cancer.

**Neurological disorders:** disorders of the central nervous system (brain and spinal cord), such as dementia, or of the peripheral nervous system (nerves) such as a neuropathy.

**Neuropathy:** the name given to a group of disorders involving nerves, whose symptoms range from a tingling sensation or numbness in the toes or fingers, to paralysis. It is estimated that 35% of people with AIDS have some form of neuropathy. "Peripheral neuropathy" refers to nerves outside the spinal cord, usually in the feet, legs, hands or arms.

**OI:** (abbreviation) *see* Opportunistic infection.

**Opportunistic infection (OI):** illness which would not normally occur in someone whose immune system is functioning properly.

**Open label trial:** (also called non-masked or non-randomized trial) a drug trial in which both doctors and subjects know what drug a subject is taking (and at what dose).

**p24 antibody test:** a test that measures the amount of antibodies in the blood against the p24 antigen.

**p24 antigen test:** a test that detects a protein fragment (p24) of HIV in blood and other body fluids.

**Pancreatitis:** inflammation of the pancreas which can result in severe abdominal pain. Pancreatitis can be a side effect of a drug, but can occur for other reasons as well, including gallstones, viral infection and excessive alcohol intake.

**PCP:** (abbreviation) *see Pneumocystis carinii* Pneumonia.

**Pharmacokinetics:** the study of how drugs are absorbed, processed and eliminated by the body. This helps in determining the best route of administration, dosage and dosing schedule.

**Phase I clinical trials:** toxicity and dose-finding clinical studies which evaluate the drug's actions in the body, its safe dosage range, how it is absorbed, distributed, metabolized and excreted from the body. These trials are usually completed within a year and involve a small number of research subjects.

**Phase II clinical trials:** efficacy studies which often include several hundred human volunteers. They are designed to assess the drug's effectiveness precisely and to detect major adverse reactions (side effects).

**Phase III clinical trials:** involve up to several thousand human subjects to confirm earlier findings of effectiveness and to detect side effects that occur only rarely or after a long period of treatment. Phase III trials may last several years.

**Placebo:** an inactive substance against which test drugs (active or "real" drugs) are compared. In placebo-controlled trials the control group takes a placebo, while the test group takes an experimental drug. Many such studies are double-blinded so that neither the patients nor their doctors know which substance the patients are receiving. Placebos are usually harmless.

**Platelets (also called thrombocytes):** blood cells which help the normal clotting of blood.

***Pneumocystis carinii* Pneumonia (PCP):** a type of pneumonia caused by a common parasite which grows rapidly in the lungs of people with AIDS. PCP is the leading cause of death in AIDS. Rarely, *Pneumocystis carinii* infections may occur elsewhere in the body, for example in skin, eye, spleen, liver or heart.

**PO:** Oral; taken by mouth as pill or liquid.

**Prophylaxis:** treatment intended to prevent people from getting a disease. For example, aerosolized pentamidine and Septra® have been shown to be effective for prophylaxis against PCP.

**Protocol:** detailed plan which states a clinical trial's rationale, goal, hypothesis, the drugs involved, dosage levels, methods of administration and treatment durations, as well as who may participate, their disease and its severity.

**Radiation therapy:** a treatment for cancer using radiation.

**Randomized trial:** in a randomized trial, participants are assigned by chance to receive one of the treatments being studied.

**Remission:** when the symptoms of a condition disappear. "Remission" is not the same as "cure," because a disease can sometimes come back after it has been in remission.

**Renal disease:** disease of the kidney.

**Retinitis:** inflammation of the retina, a part of the eye. In people with AIDS, retinitis is often caused by CMV or HSV infections. If left untreated, it leads in most cases to blindness.

**Salvage therapy:** treatment for patients who are non-responsive to or cannot tolerate other available treatments for a particular condition.

**Side effects:** an unintended effect of a drug. Some side effects are unwanted, harmful or poisonous (toxic), and are called "adverse reactions."

**Spinal tap:** *see* Lumbar puncture.

**STD:** sexually transmitted disease.

**Study:** a general term for any of a variety of research activities involving the collection, analysis or interpretation of data.

**Subcutaneous (SC):** injected directly under the skin.

**Symptom:** any condition occurring because of a disease. For example, coughing is one symptom of *Pneumocystis* pneumonia, and headaches are a symptom of cryptococcal meningitis.

**T-cells (CD4 cells):** also called T4 cells or T-helper cells. The T4 cell enhances the immune response to an infection through a complex series of interactions with other types of cells.

**Thrush:** a *Candida* infection of the mouth and throat often found in people with HIV infection.

**Toxicity:** the degree to which a medicine is poisonous. Clinical trials determine how much of a drug can be taken safely without having a toxic effect.

**Toxoplasmosis ("toxo"):** a disease caused by a parasite, *Toxoplasma gondii*, often involving the brain, eyes, heart, liver and lungs.

**Vaccine:** a substance that contains all or a portion of a disease-causing organism (usually "killed" by heat or chemicals) given for prevention or treatment of a disease. By stimulating production of antibodies, the vaccine helps to protect against infection by that organism.

**Virus:** microscopic agent which requires a living cell in order to reproduce. When viruses infect cells they can cause disease, often killing the cells they infect. Important viruses include Human immunodeficiency virus (HIV), Herpes and Cytomegalovirus (CMV).

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## Individualized Computer Search for Bay Area HIV Clinical Drug Trials

### Answer a Brief List of Questions and You Will Receive a Computerized List of Trials For Which You Qualify

**Confused by all the trials and their entrance criteria?**

**Think you are missing out on a drug that might be beneficial to you?**

| | |
|---|---|
| Study Name | A Randomized, Double Blind Study of the Efficacy and Safety of Oral Ganciclovir for the Prevention of CMV Disease in People Infected with the Human Immunodeficiency Virus |
| Study Description | The primary objective of this study is to determine the efficacy of oral ganciclovir in the prevention of CMV disease in people who have CD4 counts of 100 or less. Patients will be randomized to receive either oral ganciclovir or placebo. Two thirds will get oral ganciclovir and one third placebo. Patients must be CMV positive. |
| 1st Treatment | CMV - Prophylaxis |
| Investigator | |
| Research Nurse | Ann Conroy, RN, Davies |
| Telephone | (415) 565-6649 |
| Research Nurse | John Sayer, RN, Mt. Zion |
| Telephone | (415) 476-6536 |
| Research Nurse | Carole Ferrell, RN, E. Bay AIDS |
| Telephone | (510) 204-1291 |

## Trials Search

**A Community Service of the Institute for HIV Research and Treatment at Davies Medical Center. A 501(c)3 Non - Profit Organization**
**Call Jay Seward at (415) 565-6368**

**Trials Search is also available through:**
**San Francisco AIDS Foundation Client Services**

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